

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Overall	Overall	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	6/283 (2.1%)	7/283 (2.5%)
		OR (95% CI) p value	0.8563 (0.2837, 2.5846) 0.783	
		RD (95% CI) p value	-0.3686 (-2.8337, 2.0965) 0.769	
		RR (95% CI) p value	0.8638 (0.2944, 2.5345) 0.790	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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18OCT2019 12:35

Table 2.01
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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	<35	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	3/143 (2.1%)	5/145 (3.4%)
		OR (95% CI)	0.5452 (0.1255, 2.3681)	
		p value	0.418	
		RD (95% CI)	-1.7323 (-5.5168, 2.0522)	
		p value	0.370	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.01
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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	35-<50	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	2/107 (1.9%)	1/109 (0.9%)
		OR (95% CI) p value	1.7080 (0.1488, 19.5988) 0.667	
		RD (95% CI) p value	0.6941 (-2.4661, 3.8543) 0.667	
		RR (95% CI) p value P value for interaction	1.6494 (0.1537, 17.6953) 0.679 NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 12:35

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	≥ 50	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	1/33 (3.0%)	1/29 (3.4%)
		OR (95% CI) p value	1.2361 (0.0659, 23.1897) 0.887	
		RD (95% CI) p value	0.8391 (-7.8138, 9.4921) 0.849	
		RR (95% CI) p value P value for interaction	NC NC NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Gender at Birth	Female	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	3/63 (4.8%)	1/64 (1.6%)
		OR (95% CI) p value	3.1176 (0.3140, 30.9592) 0.332	
		RD (95% CI) p value	3.1509 (-2.9012, 9.2031) 0.308	
		RR (95% CI) p value	3.0000 (0.3221, 27.9420) 0.335	
		P value for interaction	0.147	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 12:35

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Gender at Birth	Male	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3/220 (1.4%)	6/219 (2.7%)
		OR (95% CI)	0.4859 (0.1194, 1.9769)	
		p value	0.313	
		RD (95% CI)	-1.3864 (-4.0271, 1.2544)	
		p value	0.303	
		RR (95% CI)	0.4995 (0.1270, 1.9638)	
		p value	0.320	
		P value for interaction	0.147	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20)HIV-1 RNA (<100,000, \geq 100,000 c/mL). Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Race	White	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	6/216 (2.8%)	5/201 (2.5%)
		OR (95% CI) p value	1.1268 (0.3371, 3.7669) 0.846	
		RD (95% CI) p value	0.1774 (-2.8775, 3.2322) 0.909	
		RR (95% CI) p value P value for interaction	1.1351 (0.3531, 3.6494) 0.832 0.124	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 12:35

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Race	Non-White	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	0/67	2/80 (2.5%)
		OR (95% CI) p value	0.0000 (0.0000, I) 1.000	
		RD (95% CI) p value	-2.2634 (-5.5534, 1.0267) 0.178	
		RR (95% CI) p value P value for interaction	NC NC 0.124	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20)HIV-1 RNA (<100,000, \geq 100,000 c/mL). Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	North America	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	1/47 (2.1%)	2/62 (3.2%)
		OR (95% CI) p value	0.6585 (0.0554, 7.8274) 0.741	
		RD (95% CI) p value	-1.0383 (-7.0634, 4.9868) 0.736	
		RR (95% CI) p value P value for interaction	0.7023 (0.0681, 7.2458) 0.767 0.985	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, \geq 100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20)HIV-1 RNA (<100,000, \geq 100,000 c/mL). Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 12:35

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	Europe	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	5/213 (2.3%)	5/192 (2.6%)
		OR (95% CI) p value	0.9122 (0.2590, 3.2122) 0.886	
		RD (95% CI) p value	-0.3156 (-3.3532, 2.7220) 0.839	
		RR (95% CI) p value P value for interaction	0.9254 (0.2727, 3.1403) 0.901 0.985	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	Rest of World	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	0/23	0/29
		OR (95% CI)	NC	
		p value	NC	
		RD (95% CI)	NC	
		p value	NC	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	0.985	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 12:35

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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	4/227 (1.8%)	5/227 (2.2%)
		OR (95% CI) p value	0.7955 (0.2102, 3.0110) 0.736	
		RD (95% CI) p value	-0.4405 (-3.0074, 2.1263) 0.737	
		RR (95% CI) p value P value for interaction	0.8101 (0.2210, 2.9693) 0.751 0.848	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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18OCT2019 12:35

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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	$\geq 100,000$	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	2/56 (3.6%)	2/56 (3.6%)
		OR (95% CI) p value	0.9778 (0.1319, 7.2504) 0.982	
		RD (95% CI) p value	-0.0768 (-6.9283, 6.7747) 0.982	
		RR (95% CI) p value P value for interaction	0.9787 (0.1439, 6.6581) 0.982 0.848	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, $\geq 100,000$ c/mL). Zero counts for subjects with HIV-1 RNA ≥ 50 c/mL in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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18OCT2019 12:35

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Overall	Overall	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	265/283 (94%)	264/283 (93%)
		OR (95% CI) p value	1.0598 (0.5438, 2.0651) 0.865	
		RD (95% CI) p value	0.3876 (-3.6856, 4.4608) 0.852	
		RR (95% CI) p value	1.0077 (0.9634, 1.0541) 0.737	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	<35	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	134/143 (94%)	132/145 (91%)
		OR (95% CI) p value	1.5415 (0.6321, 3.7593) 0.341	
		RD (95% CI) p value	3.3050 (-2.9018, 9.5118) 0.297	
		RR (95% CI) p value P value for interaction	1.0542 (0.9852, 1.1279) 0.126 0.176	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis
 adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA
 (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and
 subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and
 Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only
 and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment,
 gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	35-<50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	101/107 (94%)	104/109 (95%)
		OR (95% CI)	0.9137 (0.2660, 3.1385)	
		p value	0.886	
		RD (95% CI)	-0.5645 (-6.3803, 5.2513)	
		p value	0.849	
		RR (95% CI)	1.0150 (0.9348, 1.1020)	
		p value	0.724	
		P value for interaction	0.176	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Age (years)	>=50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	30/33 (91%)	28/29 (97%)
		OR (95% CI) p value	0.3326 (0.0307, 3.5981) 0.365	
		RD (95% CI) p value	-6.0363 (-17.5864, 5.5139) 0.306	
		RR (95% CI) p value P value for interaction	0.9256 (0.7468, 1.1471) 0.480 0.176	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

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Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Gender at Birth	Female	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	58/63 (92%)	61/64 (95%)
		OR (95% CI) p value	0.5765 (0.1307, 2.5428) 0.467	
		RD (95% CI) p value	-3.1509 (-11.5491, 5.2473) 0.462	
		RR (95% CI) p value P value for interaction	0.9761 (0.8686, 1.0969) 0.684 0.292	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Gender at Birth	Male	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	207/220 (94%)	203/219 (93%)
		OR (95% CI) p value	1.2591 (0.5897, 2.6885) 0.552	
		RD (95% CI) p value	1.4109 (-3.2379, 6.0596) 0.552	
		RR (95% CI) p value P value for interaction	1.0238 (0.9750, 1.0749) 0.345 0.292	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Race	White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	199/216 (92%)	192/201 (96%)
		OR (95% CI) p value	0.5493 (0.2389, 1.2628) 0.158	
		RD (95% CI) p value	-3.2421 (-7.8275, 1.3432) 0.166	
		RR (95% CI) p value P value for interaction	0.9666 (0.9165, 1.0194) 0.210 <.001	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Race	Non-White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	66/67 (99%)	70/80 (88%)
		OR (95% CI) p value	9.2712 (1.1498, 74.7554) 0.037	
		RD (95% CI) p value	10.4938 (2.5361, 18.4516) 0.010	
		RR (95% CI) p value P value for interaction	1.1050 (0.8535, 1.4308) 0.449 <.001	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	North America	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	45/47 (96%)	58/62 (94%)
		OR (95% CI) p value	1.5129 (0.2629, 8.7068) 0.643	
		RD (95% CI) p value	2.1655 (-6.6057, 10.9367) 0.628	
		RR (95% CI) p value P value for interaction	1.0541 (0.8307, 1.3374) 0.665 0.640	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	Europe	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	198/213 (93%)	179/192 (93%)
		OR (95% CI) p value	0.9582 (0.4435, 2.0703) 0.914	
		RD (95% CI) p value	-0.1091 (-5.0429, 4.8247) 0.965	
		RR (95% CI) p value P value for interaction	1.0003 (0.9485, 1.0549) 0.992 0.640	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Region	Rest of World	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	22/23 (96%)	27/29 (93%)
		OR (95% CI) p value	1.1680 (0.0933, 14.6262) 0.904	
		RD (95% CI) p value	0.7945 (-12.9734, 14.5623) 0.910	
		RR (95% CI) p value P value for interaction	1.0097 (0.7812, 1.3050) 0.941 0.640	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis
 adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA
 (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and
 subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and
 Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only
 and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment,
 gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	215/227 (95%)	211/227 (93%)
		OR (95% CI) p value	1.3590 (0.6276, 2.9424) 0.436	
		RD (95% CI) p value	1.7621 (-2.6677, 6.1919) 0.436	
		RR (95% CI) p value P value for interaction	1.0231 (0.9758, 1.0727) 0.345 0.196	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis
 adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA
 (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and
 subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and
 Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only
 and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment,
 gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup	Category	Measure	Q4W IM (N=283)	ABC/DTG/3TC (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	50/56 (89%)	53/56 (95%)
		OR (95% CI)	0.4767 (0.1118, 2.0333)	
		p value	0.317	
		RD (95% CI)	-5.1873 (-15.1218, 4.7472)	
		p value	0.306	
		RR (95% CI)	0.9617 (0.8399, 1.1013)	
		p value	0.572	
		P value for interaction	0.196	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis
 adjusting for gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA
 (<100,000, >=100,000 c/mL).
 OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and
 subgroups (using a 'by subgroup statement'), adjusting for gender at birth (female, male) and
 Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL). p value for interaction is for RR only
 and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment,
 gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL).

PPD

18OCT2019 12:36

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

Subgroup: Overall

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q4W IM	283	Maintenance BL (Day 1)	283	666.4	272.14	624.0	473.0	839.0	109	1889
			Week 48	246	703.2	285.75	673.5	493.0	865.0	134	1694
			Change	246	40.2	195.17	45.5	-60.0	141.0	-1228	683
	ABC/DTG/3TC	283	Maintenance BL (Day 1)	283	645.7	253.44	625.0	472.0	799.0	66	1558
			Week 48	263	731.2	272.49	718.0	536.0	899.0	114	1903
			Change	263	79.9	194.55	80.0	-32.0	193.0	-450	985

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

PPD

09OCT2019 10:38

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

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

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
<35	Q4W IM	143	Maintenance BL (Day 1)	143	680.8	271.03	650.0	480.0	847.0	166	1889
			Week 48	128	727.4	286.47	671.0	504.5	907.5	188	1651
			Change	128	41.8	215.64	56.0	-56.5	149.0	-1228	683
	ABC/DTG/3TC	145	Maintenance BL (Day 1)	145	672.1	265.29	641.0	496.0	816.0	66	1558
			Week 48	131	764.2	285.46	742.0	567.0	924.0	114	1903
			Change	131	86.6	216.36	84.0	-35.0	219.0	-450	985
35-<50	Q4W IM	107	Maintenance BL (Day 1)	107	654.4	284.46	596.0	457.0	841.0	109	1557
			Week 48	90	663.9	270.98	650.5	483.0	815.0	196	1554
			Change	90	32.1	156.30	24.5	-66.0	123.0	-656	482
	ABC/DTG/3TC	109	Maintenance BL (Day 1)	109	615.7	216.15	589.0	444.0	760.0	98	1117
			Week 48	104	697.6	237.38	682.5	538.0	863.5	236	1352
			Change	104	72.9	164.74	80.5	-29.0	191.5	-416	518
>=50	Q4W IM	33	Maintenance BL (Day 1)	33	642.9	238.04	649.0	473.0	827.0	132	1090
			Week 48	28	718.8	323.53	697.0	546.5	936.5	134	1694
			Change	28	58.9	214.01	81.5	-67.0	178.5	-560	604
	ABC/DTG/3TC	29	Maintenance BL (Day 1)	29	626.8	311.94	589.0	397.0	800.0	198	1446
			Week 48	28	702.1	320.47	704.0	389.0	982.5	193	1210
			Change	28	74.0	194.75	58.0	-25.5	142.5	-407	627

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

PPD

09OCT2019 10:38

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

Subgroup: Gender at Birth (Female vs. Male)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Female	Q4W IM	63	Maintenance BL (Day 1)	63	630.5	334.98	536.0	410.0	826.0	166	1889
			Week 48	59	648.2	293.18	613.0	419.0	811.0	144	1651
			Change	59	19.1	228.06	34.0	-57.0	129.0	-1228	443
	ABC/DTG/3TC	64	Maintenance BL (Day 1)	64	586.2	225.68	540.0	429.0	725.5	198	1228
			Week 48	60	686.9	277.77	632.5	534.0	880.0	193	1309
			Change	60	112.2	159.90	110.5	5.0	206.5	-310	626
Male	Q4W IM	220	Maintenance BL (Day 1)	220	676.7	251.23	649.5	496.0	847.0	109	1613
			Week 48	187	720.5	281.93	684.0	518.0	882.0	134	1694
			Change	187	46.8	183.76	49.0	-72.0	146.0	-656	683
	ABC/DTG/3TC	219	Maintenance BL (Day 1)	219	663.1	258.90	639.0	494.0	816.0	66	1558
			Week 48	203	744.3	270.21	738.0	541.0	906.0	114	1903
			Change	203	70.3	203.04	68.0	-60.0	190.0	-450	985

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

PPD

09OCT2019 10:38

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

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
White	Q4W IM	216	Maintenance BL (Day 1)	216	671.7	275.52	637.0	487.5	828.0	109	1889
			Week 48	187	713.7	285.31	678.0	509.0	884.0	134	1694
			Change	187	43.6	204.55	61.0	-60.0	149.0	-1228	604
	ABC/DTG/3TC	201	Maintenance BL (Day 1)	201	653.0	261.57	632.0	472.0	807.0	66	1558
			Week 48	192	739.0	280.47	736.5	537.5	907.0	114	1903
			Change	192	83.8	195.59	80.0	-30.5	200.0	-431	985
Non-White	Q4W IM	67	Maintenance BL (Day 1)	67	649.4	262.23	573.0	454.0	839.0	166	1394
			Week 48	59	669.9	287.00	623.0	470.0	778.0	196	1422
			Change	59	29.3	162.99	1.0	-72.0	91.0	-346	683
	ABC/DTG/3TC	80	Maintenance BL (Day 1)	80	625.9	227.80	623.0	481.5	750.0	98	1282
			Week 48	69	716.9	249.36	697.0	550.0	879.0	248	1408
			Change	69	77.8	184.68	84.0	-27.0	179.0	-312	538

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

PPD

09OCT2019 10:38

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

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

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
North America	Q4W IM	47	Maintenance BL (Day 1)	47	686.3	234.52	660.0	469.0	855.0	213	1138
			Week 48	40	753.7	311.08	701.0	513.5	937.5	314	1422
			Change	40	88.5	203.11	64.0	-66.0	197.0	-346	683
	ABC/DTG/3TC	62	Maintenance BL (Day 1)	62	614.1	314.10	560.0	375.0	861.0	66	1437
			Week 48	57	672.2	296.05	697.0	445.0	912.0	114	1337
			Change	57	55.1	208.35	62.0	-27.0	180.0	-450	557
Europe	Q4W IM	213	Maintenance BL (Day 1)	213	673.5	280.88	627.0	488.0	825.0	109	1889
			Week 48	185	709.1	281.82	678.0	517.0	871.0	134	1694
			Change	185	36.1	200.41	53.0	-60.0	141.0	-1228	604
	ABC/DTG/3TC	192	Maintenance BL (Day 1)	192	660.1	239.39	642.0	495.0	799.5	198	1558
			Week 48	179	755.2	265.32	736.0	577.0	905.0	193	1903
			Change	179	87.9	193.43	84.0	-32.0	202.0	-407	985
Rest of World	Q4W IM	23	Maintenance BL (Day 1)	23	559.9	246.68	495.0	403.0	703.0	166	1101
			Week 48	21	554.8	228.63	558.0	412.0	734.0	196	988
			Change	21	-15.7	92.48	-38.0	-59.0	42.0	-204	214
	ABC/DTG/3TC	29	Maintenance BL (Day 1)	29	617.7	191.35	620.0	509.0	707.0	228	1097
			Week 48	27	696.6	254.32	706.0	514.0	858.0	314	1309
			Change	27	78.7	173.10	85.0	-21.0	174.0	-277	538

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

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

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
<100,000	Q4W IM	227	Maintenance BL (Day 1)	227	684.9	275.15	648.0	487.0	847.0	109	1889
			Week 48	201	725.6	282.57	689.0	521.0	871.0	144	1694
			Change	201	44.3	202.12	58.0	-52.0	144.0	-1228	683
	ABC/DTG/3TC	227	Maintenance BL (Day 1)	227	664.0	249.59	639.0	496.0	807.0	66	1558
			Week 48	209	738.3	265.94	723.0	572.0	881.0	114	1903
			Change	209	68.9	196.60	71.0	-37.0	180.0	-450	985
>=100,000	Q4W IM	56	Maintenance BL (Day 1)	56	591.7	248.08	553.0	437.5	798.0	132	1132
			Week 48	45	603.1	281.40	592.0	405.0	783.0	134	1259
			Change	45	21.8	161.21	-1.0	-83.0	127.0	-248	482
	ABC/DTG/3TC	56	Maintenance BL (Day 1)	56	571.6	257.70	512.0	379.5	752.5	98	1275
			Week 48	54	703.9	297.55	689.0	399.0	970.0	252	1337
			Change	54	122.5	181.94	88.0	20.0	212.0	-156	627

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

PPD

09OCT2019 10:38

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	246	40.61	11.611	-36.11 (-68.08, -4.13)	0.027	-0.1903 (0.08876)	(-0.3646, -0.0159)	0.033
ABC/DTG/3TC	283	263	76.72	11.403					

[1] Adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from MMRM with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q4W IM - ABC/DTG/3TC.

Note: MMRM = Mixed Model Repeated Measures.

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	143	128	44.06	16.343	-40.83 (-85.97, 4.32)	0.076	0.468	-0.1544 (0.12420)	(-0.3984, 0.0896)	0.214
ABC/DTG/3TC	145	131	84.88	16.197						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	107	90	27.66	19.282	-40.20 (-92.44, 12.03)	0.131	0.468	-0.1315 (0.14382)	(-0.4140, 0.1510)	0.361
ABC/DTG/3TC	109	104	67.87	18.319						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	33	28	64.45	34.652	-4.81 (-101.78, 92.15)	0.922	0.468	-0.0085 (0.26688)	(-0.5327, 0.5158)	0.975
ABC/DTG/3TC	29	28	69.27	35.244						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	63	59	12.91	24.186	-83.84 (-150.67, -17.02)	0.014	0.625	-0.2157 (0.18320)	(-0.5756, 0.1442)	0.240
ABC/DTG/3TC	64	60	96.75	23.972						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	220	187	48.58	13.333	-22.23 (-58.78, 14.32)	0.233	0.625	-0.1034 (0.10127)	(-0.3023, 0.0956)	0.308
ABC/DTG/3TC	219	203	70.81	12.990						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	216	187	45.80	13.379	-36.67 (-73.81, 0.48)	0.053	0.296	-0.1689 (0.10273)	(-0.3707, 0.0329)	0.101
ABC/DTG/3TC	201	192	82.47	13.368						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	67	59	23.79	23.755	-45.64 (-109.34, 18.07)	0.160	0.296	-0.1219 (0.17711)	(-0.4698, 0.2260)	0.491
ABC/DTG/3TC	80	69	69.43	22.129						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	47	40	84.91	28.656	37.08 (-36.97, 111.13)	0.326	0.005	0.0864 (0.20599)	(-0.3183, 0.4910)	0.675
ABC/DTG/3TC	62	57	47.82	24.507						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	213	185	38.26	13.442	-48.55 (-86.39, -10.72)	0.012	0.005	-0.2196 (0.10491)	(-0.4257, -0.0135)	0.037
ABC/DTG/3TC	192	179	86.81	13.800						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

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

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	23	21	-28.72	40.286	-99.00 (-204.14, 6.14)	0.065	0.005	-0.1622 (0.29059)	(-0.7330, 0.4087)	0.577
ABC/DTG/3TC	29	27	70.28	35.469						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.
 [2] Difference: Q4W IM - ABC/DTG/3TC.
 [3] Inter = Interaction between each subgroup and treatment.

Table 2.05

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

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)
 Category: <100,000

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	227	201	45.98	12.959	-22.62 (-58.36, 13.13)	0.215	0.432	-0.1080 (0.09871)	(-0.3019, 0.0859)	0.274
ABC/DTG/3TC	227	209	68.59	12.786						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - ABC/DTG/3TC.

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

Table 2.05

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

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)
 Category: >=100,000

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	56	45	16.25	26.987	-92.08 (-164.68, -19.47)	0.013	0.432	-0.2158 (0.20167)	(-0.6119, 0.1804)	0.285
ABC/DTG/3TC	56	54	108.33	25.376						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) CD4+ Cell Count (cells/mm³), gender at birth (female, male), Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ Cell Count, i.e., the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.
 [2] Difference: Q4W IM - ABC/DTG/3TC.
 [3] Inter = Interaction between each subgroup and treatment.

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

Subgroup: Overall

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall	0/283	1/283 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

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

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

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

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/33	1/29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

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

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

Subgroup: Gender at Birth (Female vs. Male)

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Female	0/63	0/64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

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

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

Subgroup: Race (White vs. Non-White)

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/67	0/80	NC	NC	NC	

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

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

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

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
North America	0/47	0/62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/23	0/29	NC	NC	NC	

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

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

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/56	0/56	NC	NC	NC	

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

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	258	53.425	8.5070	55.120	50.100	59.270	14.27	67.70	
				BL (Day 1)									
				Week 24	276	53.462	8.4127	55.120	49.095	60.070	18.77	67.70	
				Week 48	263	53.497	8.9026	55.640	49.290	60.160	18.20	69.66	
	ABC/DTG/3TC	283	Maintenance	267	52.913	8.6524	54.590	48.770	59.690	13.40	68.52		
			BL (Day 1)										
			Week 24	270	51.968	9.3476	53.145	47.390	59.600	7.91	70.18		
			Week 48	266	51.982	9.1531	54.170	46.830	59.450	22.04	67.95		
Age (years) <35	Q4W IM	143	Maintenance	129	52.748	9.3368	55.170	48.540	59.600	14.27	64.23		
			BL (Day 1)										
			Week 24	137	53.590	8.4164	55.140	49.330	60.160	19.66	63.36		
			Week 48	133	53.298	9.5804	55.620	49.550	60.160	18.20	69.66		
	ABC/DTG/3TC	145	Maintenance	134	52.021	8.6428	52.950	47.650	57.910	13.40	68.52		
			BL (Day 1)										
			Week 24	139	51.036	9.3988	52.270	46.930	57.900	7.91	68.13		
			Week 48	133	51.727	9.3065	54.020	47.100	57.850	22.04	67.95		
			W48 CFB	123	0.222	9.8943	0.000	-4.570	5.100	-35.24	24.37		

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

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Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	54.754	6.4245	55.280	52.240	59.600	26.72	67.70	
				BL (Day 1)									
				Week 24	106	53.675	7.7456	54.825	49.570	60.070	32.39	67.70	
				Week 48	101	53.964	7.5031	55.900	48.800	60.070	34.22	66.92	
				W48 CFB	93	-0.489	6.9407	-0.100	-3.400	2.820	-23.95	30.56	
				ABC/DTG/3TC	109	54.218	8.2064	57.310	50.850	59.960	21.71	66.00	
	>=50	Q4W IM	33	Maintenance	30	51.952	10.3330	54.600	48.130	58.140	22.29	62.38	
				BL (Day 1)									
				Week 24	33	52.248	10.4192	54.590	48.490	59.690	18.77	62.48	
				Week 48	29	52.790	10.3132	54.410	47.060	60.730	23.62	63.26	
				W48 CFB	26	1.156	8.5212	0.715	-2.790	4.000	-15.96	23.95	
				ABC/DTG/3TC	29	52.359	9.9103	56.900	46.050	60.320	30.21	64.44	
>=50	ABC/DTG/3TC	29	Maintenance	29	52.359	9.9103	56.900	46.050	60.320	30.21	64.44		
			BL (Day 1)										
			Week 24	29	51.311	9.0390	51.180	43.750	59.690	32.36	62.63		
			Week 48	29	51.195	8.8234	52.330	43.650	57.380	30.11	63.07		
			W48 CFB	29	-1.164	7.9115	-2.350	-5.880	0.390	-15.79	20.60		

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	54.239	8.2683	57.380	49.990	60.115	24.25	64.23	
				BL (Day 1)									
				Week 24	61	54.125	10.0088	57.380	49.630	61.200	18.77	63.26	
				Week 48	59	53.910	9.6789	57.380	45.900	62.380	24.82	66.74	
		W48 CFB	52	0.240	6.9992	0.725	-2.315	2.950	-23.22	19.22			
		ABC/DTG/3TC	64	Maintenance	59	54.811	7.5235	57.380	50.230	60.320	31.05	64.87	
				BL (Day 1)									
				Week 24	61	53.737	9.4899	56.920	50.100	60.320	26.39	70.18	
	Week 48			61	53.587	8.7106	54.750	47.450	62.380	30.11	65.89		
	W48 CFB	56	-1.176	7.7192	-0.110	-4.850	2.640	-22.61	19.41				
			Male	Q4W IM	220	Maintenance	202	53.199	8.5784	55.060	50.760	58.220	14.27
BL (Day 1)													
Week 24	215	53.274				7.9183	54.750	49.020	59.600	25.07	67.70		
Week 48	204	53.378				8.6869	55.230	49.575	60.070	18.20	69.66		
W48 CFB	188	0.036	7.5952	0.000	-3.340	3.570	-23.95	30.56					
ABC/DTG/3TC	219	Maintenance	208	52.375	8.8896	54.420	47.700	58.445	13.40	68.52			
		BL (Day 1)											
		Week 24	209	51.452	9.2649	52.670	47.020	58.420	7.91	68.13			
		Week 48	205	51.504	9.2474	53.930	46.050	57.900	22.04	67.95			
W48 CFB	195	-0.580	9.0700	-0.010	-5.100	3.040	-35.24	24.37					

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	198	53.403	8.5989	55.090	51.050	59.600	14.27	67.70	
				BL (Day 1)									
				Week 24	210	53.668	8.0997	55.160	49.490	59.860	18.77	67.70	
				Week 48	198	53.717	8.7006	55.630	49.820	60.160	18.20	69.66	
				W48 CFB	182	0.194	7.7847	0.100	-2.780	3.930	-23.22	30.56	
				ABC/DTG/3TC	201	53.376	7.8275	54.590	49.410	59.850	29.73	66.00	
	Non-White	Q4W IM	67	Maintenance	60	53.496	8.2667	55.490	50.060	58.295	23.14	62.48	
				BL (Day 1)									
				Week 24	66	52.810	9.3759	54.780	47.390	60.160	19.66	63.26	
				Week 48	65	52.830	9.5311	55.780	46.750	60.160	24.82	64.14	
				W48 CFB	58	-0.275	6.3647	-0.125	-3.660	3.430	-23.95	19.22	
				ABC/DTG/3TC	80	51.613	10.5570	54.750	45.260	58.410	13.40	68.52	
ABC/DTG/3TC	80	Maintenance	73	51.613	10.5570	54.750	45.260	58.410	13.40	68.52			
		BL (Day 1)											
		Week 24	74	50.204	11.3412	52.225	43.270	58.410	7.91	70.18			
		Week 48	71	51.060	10.0885	53.310	43.110	59.600	27.98	66.72			
W48 CFB	64	-0.630	11.0892	-0.065	-8.315	5.155	-26.64	23.67					

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	49.507	12.0206	54.545	45.390	57.380	14.27	62.48	
				BL (Day 1)									
				Week 24	46	50.553	9.3526	52.020	45.780	57.530	19.66	62.48	
				Week 48	45	51.292	10.6223	54.950	46.610	57.850	18.20	69.66	
			W48 CFB		38	1.304	7.0869	0.330	-2.780	3.930	-13.38	23.95	
		ABC/DTG/3TC		62	Maintenance	58	52.950	10.3691	57.280	49.370	60.160	21.71	66.00
	BL (Day 1)												
	Week 24				59	51.498	10.9470	54.750	45.610	59.690	7.91	62.48	
	Week 48				57	51.158	9.2252	52.260	46.050	57.380	22.04	62.48	
			W48 CFB		53	-1.692	9.9127	-0.340	-5.580	4.850	-35.24	24.37	
	Europe	Q4W IM		213	Maintenance	196	53.919	7.5481	55.145	51.055	58.925	22.29	67.70
					BL (Day 1)								
Week 24					208	53.769	8.2009	55.230	49.600	60.070	18.77	67.70	
Week 48					196	53.663	8.4122	55.355	49.580	60.160	23.62	66.92	
			W48 CFB		181	-0.264	7.4442	0.000	-2.910	3.430	-23.22	30.56	
		ABC/DTG/3TC		192	Maintenance	182	53.074	7.6271	54.590	48.770	59.170	30.21	68.52
BL (Day 1)													
Week 24					182	52.010	8.7549	52.810	47.390	59.460	26.39	65.35	
Week 48	181				51.867	9.0260	53.310	47.060	58.420	23.60	67.95		
		W48 CFB		172	-0.830	7.8590	-0.035	-4.940	2.550	-26.64	21.95		

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q4W IM	23	Maintenance	22	56.147	7.0001	57.700	51.890	62.380	39.56	62.38
				BL (Day 1)	22	56.645	6.8061	58.960	50.990	62.380	39.82	63.26
				Week 24	22	56.533	8.6590	60.160	49.880	62.380	34.62	64.14
				Week 48	21	0.838	8.2580	1.410	-2.310	2.820	-23.95	19.22
		ABC/DTG/3TC	29	Maintenance	27	51.750	11.1195	55.050	47.650	59.190	13.40	63.52
				BL (Day 1)	29	52.661	9.7344	52.960	47.920	62.380	32.30	70.18
				Week 24	28	54.403	9.7486	57.930	48.030	62.380	35.44	66.72
				Week 48	26	2.057	11.5383	0.505	-3.300	9.740	-22.61	23.67
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance	206	53.193	8.7769	55.120	50.040	59.600	14.27	67.70
				BL (Day 1)	221	53.210	8.6152	55.120	48.070	60.070	18.77	67.70
				Week 24	212	53.390	9.0342	55.780	48.210	60.160	18.20	69.66
				Week 48	192	0.159	7.1649	0.100	-2.780	3.765	-23.22	30.56
		ABC/DTG/3TC	227	Maintenance	214	53.031	8.4515	54.590	49.170	59.170	13.40	68.52
				BL (Day 1)	217	52.124	9.1807	53.080	47.400	59.460	7.91	70.18
				Week 24	212	51.925	9.3548	54.465	47.390	59.085	22.04	67.95
				Week 48	200	-0.705	9.0908	-0.005	-4.940	2.785	-35.24	23.67

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance	52	54.344	7.3455	55.540	52.435	58.245	29.92	62.63	
				BL (Day 1)									
				Week 24	55	54.476	7.5319	55.120	50.120	62.380	33.32	63.36	
				Week 48	51	53.944	8.4040	55.190	50.100	60.160	25.24	62.85	
				W48 CFB	48	-0.236	8.6005	-0.045	-2.850	2.700	-23.95	24.06	
		ABC/DTG/3TC	56	Maintenance	53	52.436	9.4917	55.050	47.980	60.070	21.71	63.08	
				BL (Day 1)									
				Week 24	53	51.330	10.0688	53.240	47.080	60.070	26.39	68.13	
				Week 48	54	52.203	8.3927	52.515	45.250	59.600	32.02	66.72	
						W48 CFB	51	-0.743	7.4915	-0.130	-5.480	4.200	-15.79

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	258	55.853	4.6866	57.030	54.640	58.100	23.34	69.49	
				BL (Day 1)									
				Week 24	276	55.838	4.7255	57.125	54.690	58.215	33.14	66.11	
				Week 48	263	55.401	5.0045	56.630	53.650	58.100	36.38	65.31	
		ABC/DTG/3TC	283	Maintenance	267	55.690	5.3839	57.120	54.760	58.380	29.09	65.68	
				BL (Day 1)									
				Week 24	270	55.484	5.2819	57.120	54.060	58.380	33.33	65.74	
				Week 48	266	55.579	5.7168	57.170	54.180	58.450	33.31	75.74	
Age (years) <35		Q4W IM	143	Maintenance	129	56.113	4.7244	57.040	54.760	58.110	23.34	65.99	
				BL (Day 1)									
				Week 24	137	55.984	4.2781	57.120	54.680	58.110	39.37	64.18	
				Week 48	133	56.085	4.7602	57.120	54.640	58.570	38.00	65.31	
		ABC/DTG/3TC	145	Maintenance	134	56.122	5.7012	57.370	55.620	58.600	29.09	64.68	
				BL (Day 1)									
				Week 24	139	56.057	4.9448	57.340	54.640	59.130	40.24	64.59	
				Week 48	133	56.063	5.4304	57.410	54.700	58.890	35.79	75.74	
		W48 CFB	123	-0.362	5.6458	0.000	-3.330	1.920	-16.06	17.14			

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	55.773	4.3250	57.120	54.480	57.760	37.45	65.92	
				BL (Day 1)									
				Week 24	106	55.769	4.5938	57.340	54.640	58.380	42.67	66.11	
		Week 48	101	54.783	5.0545	56.130	53.370	57.620	36.38	65.26			
		W48 CFB	93	-0.766	5.4684	-0.280	-2.860	1.270	-15.36	16.25			
		ABC/DTG/3TC	109	56.142	3.6280	57.045	55.130	57.620	44.31	64.03			
	>=50	Q4W IM	33	Maintenance	30	55.004	5.6438	56.360	54.130	57.620	42.42	69.49	
				BL (Day 1)									
				Week 24	33	55.452	6.6793	57.120	55.970	58.600	33.14	63.74	
		Week 48	29	54.413	5.6276	56.130	51.520	57.620	39.25	63.47			
		W48 CFB	26	-0.547	6.0028	0.050	-2.570	1.690	-15.39	13.35			
		ABC/DTG/3TC	29	52.069	7.5712	54.640	47.900	57.120	35.22	65.68			
				Maintenance	29	52.069	7.5712	54.640	47.900	57.120	35.22	65.68	
				BL (Day 1)									
				Week 24	29	52.537	6.9489	54.690	49.150	57.620	33.33	61.23	
				Week 48	29	50.371	8.5827	53.660	42.480	57.620	33.31	59.60	
				W48 CFB	29	-1.698	7.8635	0.000	-3.820	2.360	-25.36	11.94	

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	55.522	4.0029	56.995	54.640	57.620	42.42	62.12	
				BL (Day 1)									
				Week 24	61	55.114	5.1289	57.120	53.910	57.620	40.43	64.18	
				Week 48	59	54.296	5.4199	56.130	52.640	57.620	36.38	63.47	
				W48 CFB	52	-0.855	4.6313	-0.280	-3.140	1.645	-15.09	10.88	
				ABC/DTG/3TC	64	52.489	7.2293	54.920	47.240	57.620	29.09	65.68	
	Male	Q4W IM	220	Maintenance	202	55.945	4.8641	57.030	54.640	58.220	23.34	69.49	
				BL (Day 1)									
				Week 24	215	56.043	4.5966	57.230	54.760	58.380	33.14	66.11	
				Week 48	204	55.721	4.8449	56.900	54.335	58.380	39.25	65.31	
				W48 CFB	188	-0.274	5.6869	0.000	-2.230	1.490	-15.65	34.98	
				ABC/DTG/3TC	219	56.597	4.3425	57.150	55.805	58.525	32.84	64.68	
	ABC/DTG/3TC	219	Maintenance	208	56.597	4.3425	57.150	55.805	58.525	32.84	64.68		
			BL (Day 1)										
			Week 24	209	56.273	4.6876	57.340	55.340	58.880	38.62	65.74		
			Week 48	205	56.413	4.8637	57.340	55.470	58.890	38.86	75.74		
			W48 CFB	195	-0.329	4.7852	0.000	-2.470	1.920	-16.06	17.14		

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	198	55.750	4.8657	56.900	54.640	58.110	23.34	69.49	
				BL (Day 1)									
				Week 24	210	55.539	4.9696	57.120	54.370	58.100	33.14	66.11	
				Week 48	198	55.346	5.0083	56.380	53.370	57.750	38.00	65.31	
				W48 CFB	182	-0.476	5.8630	-0.100	-2.850	1.490	-15.65	34.98	
				ABC/DTG/3TC	201	55.659	5.2191	57.120	54.770	58.105	29.09	64.03	
	Non-White	Q4W IM	67	Maintenance	60	56.195	4.0583	57.120	54.980	57.975	42.42	65.59	
				BL (Day 1)									
				Week 24	66	56.790	3.7220	57.620	55.590	58.430	40.48	64.18	
				Week 48	65	55.568	5.0279	57.120	54.540	58.320	36.38	63.25	
				W48 CFB	58	-0.162	4.0376	-0.095	-1.810	1.570	-11.02	14.04	
				ABC/DTG/3TC	80	55.676	5.8721	57.120	54.640	58.600	32.84	65.68	
				Maintenance	73	55.676	5.8721	57.120	54.640	58.600	32.84	65.68	
				BL (Day 1)									
				Week 24	74	54.646	6.4243	56.820	51.770	58.680	38.62	64.59	
				Week 48	71	55.113	5.8646	57.120	52.860	58.890	35.79	65.20	
				W48 CFB	64	-0.441	5.8728	0.000	-3.820	3.065	-12.90	12.29	

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

PPD

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	56.746	5.2171	57.120	55.225	58.565	36.64	69.49	
				BL (Day 1)									
				Week 24	46	55.694	5.6038	57.340	54.280	59.010	39.37	64.18	
				Week 48	45	55.360	6.0154	56.130	53.890	58.600	36.38	65.31	
			W48 CFB	38	-0.934	3.6498	-0.495	-3.200	1.270	-9.31	10.03		
		ABC/DTG/3TC	62	Maintenance	58	55.130	6.7518	57.340	54.640	58.390	29.09	63.81	
	BL (Day 1)												
	Week 24			59	55.394	5.2288	57.120	54.140	58.110	40.22	64.59		
	Week 48			57	55.535	5.9748	57.120	54.150	58.600	38.50	75.74		
			W48 CFB	53	0.509	5.9451	0.460	-2.600	2.360	-12.90	17.14		
	Europe	Q4W IM	213	Maintenance	196	55.546	4.7111	56.885	54.600	57.620	23.34	65.92	
				BL (Day 1)									
Week 24				208	55.709	4.7204	57.120	54.640	57.995	33.14	66.11		
Week 48				196	55.415	4.8794	56.755	53.510	58.200	38.00	65.26		
			W48 CFB	181	-0.222	5.9711	0.000	-2.260	1.770	-15.65	34.98		
		ABC/DTG/3TC	192	Maintenance	182	55.778	5.0440	57.120	54.920	58.110	32.84	65.68	
BL (Day 1)													
Week 24				182	55.769	5.0061	57.120	54.250	58.600	33.33	65.74		
Week 48	181			55.646	5.7762	57.340	54.260	58.450	33.31	66.89			
		W48 CFB	172	-0.276	5.3274	0.000	-2.040	2.190	-25.36	15.92			

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

PPD

25OCT2019 10:46

Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	23	Maintenance	22	56.965	2.9102	57.620	54.660	57.620	50.36	62.12	
				BL (Day 1)									
				Week 24	22	57.357	1.6923	57.620	56.130	58.600	54.72	61.15	
				Week 48	22	55.359	3.9448	56.280	53.980	57.620	40.64	58.89	
					W48 CFB	21	-0.969	3.3280	-0.610	-1.930	0.220	-9.91	5.91
		ABC/DTG/3TC		29	Maintenance	27	56.294	4.2853	57.120	55.650	58.430	44.31	64.68
	BL (Day 1)												
	Week 24				29	53.883	6.7968	57.120	51.300	57.620	39.06	62.40	
Week 48	28				55.237	4.9138	56.860	51.935	57.620	43.10	62.21		
				W48 CFB	26	-1.002	5.4694	-0.705	-3.670	2.760	-10.85	12.29	
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance	206	55.784	5.0392	57.120	54.640	57.960	23.34	69.49	
				BL (Day 1)									
				Week 24	221	55.904	4.8245	57.120	54.760	58.380	33.14	66.11	
				Week 48	212	55.415	5.1208	56.830	53.650	58.105	36.38	65.31	
					W48 CFB	192	-0.266	5.4798	-0.070	-2.230	1.550	-15.65	34.98
		ABC/DTG/3TC		227	Maintenance	214	55.339	5.7131	57.120	54.150	58.170	29.09	64.68
	BL (Day 1)												
	Week 24				217	55.231	5.4979	56.900	53.560	58.240	33.33	64.59	
Week 48	212				55.398	5.9884	57.120	53.885	58.450	33.31	75.74		
				W48 CFB	200	-0.049	5.7250	0.000	-2.445	2.420	-25.36	17.14	

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

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Table 6.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase)
 - Overall and by Subgroup - FLAIR

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance	52	56.129	2.9176	56.375	54.640	58.240	47.43	62.12	
				BL (Day 1)									
				Week 24	55	55.574	4.3365	57.530	53.500	57.900	42.78	64.14	
				Week 48	51	55.345	4.5358	56.130	53.780	58.100	41.82	65.26	
				W48 CFB	48	-0.938	5.4630	-0.170	-4.340	1.380	-15.36	12.61	
		ABC/DTG/3TC	56	Maintenance	53	57.106	3.4679	57.340	56.130	58.450	44.50	65.68	
				BL (Day 1)									
				Week 24	53	56.523	4.1709	57.620	55.620	58.620	41.12	65.74	
				Week 48	54	56.288	4.4725	57.620	55.280	58.600	43.10	62.98	
						W48 CFB	51	-0.719	4.3423	0.160	-3.190	1.710	-12.17

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

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Table 6.02

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

Domain: Mental Component Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	240	0.06	0.453	0.98 (-0.34, 2.30)	0.147	0.1335 (0.09042)	(-0.0442, 0.3112)	0.140
ABC/DTG/3TC	283	249	-0.92	0.500					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.02

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

Domain: Physical Component Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	240	-0.33	0.291	-0.12 (-0.95, 0.72)	0.783	-0.0250 (0.09032)	(-0.2024, 0.1525)	0.782
ABC/DTG/3TC	283	249	-0.21	0.311					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	121	0.14 (0.643)	0.54 (-1.35, 2.43)	0.574	0.890	0.0517 (0.12811)	(-0.2000, 0.3034)	0.687
	ABC/DTG/3TC	145	122	-0.40 (0.716)						
35-<50	Q4W IM	107	93	-0.01 (0.734)	1.29 (-0.85, 3.42)	0.236	0.890	0.1093 (0.14458)	(-0.1748, 0.3934)	0.450
	ABC/DTG/3TC	109	98	-1.30 (0.801)						
>=50	Q4W IM	33	26	-0.01 (1.372)	1.80 (-2.14, 5.75)	0.370	0.890	0.0825 (0.26967)	(-0.4474, 0.6124)	0.760
	ABC/DTG/3TC	29	29	-1.81 (1.480)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	0.72 (0.980)	1.03 (-1.80, 3.85)	0.476	0.930	0.0657 (0.19229)	(-0.3121, 0.4436)	0.733
	ABC/DTG/3TC	64	56	-0.30 (1.064)						
Male	Q4W IM	220	188	-0.13 (0.513)	0.97 (-0.54, 2.47)	0.207	0.930	0.1161 (0.10238)	(-0.0851, 0.3173)	0.257
	ABC/DTG/3TC	219	193	-1.09 (0.569)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	182	0.18 (0.520)	0.85 (-0.68, 2.38)	0.274	0.662	0.1008 (0.10429)	(-0.1042, 0.3057)	0.334
	ABC/DTG/3TC	201	185	-0.67 (0.581)						
Non-White	Q4W IM	67	58	-0.30 (0.928)	1.37 (-1.28, 4.03)	0.310	0.662	0.0932 (0.18103)	(-0.2625, 0.4489)	0.607
	ABC/DTG/3TC	80	64	-1.68 (0.987)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	38	0.41 (1.159)	2.39 (-0.73, 5.51)	0.133	0.929	0.1387 (0.21401)	(-0.2818, 0.5592)	0.517
	ABC/DTG/3TC	62	51	-1.98 (1.099)						
Europe	Q4W IM	213	181	-0.45 (0.535)	0.72 (-0.83, 2.28)	0.361	0.929	0.0846 (0.10635)	(-0.1244, 0.2936)	0.427
	ABC/DTG/3TC	192	172	-1.17 (0.607)						
Rest of World	Q4W IM	23	21	3.68 (1.677)	0.71 (-3.57, 4.99)	0.746	0.929	0.0300 (0.29293)	(-0.5456, 0.6056)	0.919
	ABC/DTG/3TC	29	26	2.98 (1.664)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

Domain: Mental Component Score
 Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	192	0.10 (0.507)	1.09 (-0.40, 2.57)	0.151	0.957	0.1323 (0.10122)	(-0.0666, 0.3312)	0.192
	ABC/DTG/3TC	227	198	-0.98 (0.561)						
>=100,000	Q4W IM	56	48	-0.12 (1.013)	0.57 (-2.39, 3.52)	0.706	0.957	0.0348 (0.20078)	(-0.3598, 0.4293)	0.863
	ABC/DTG/3TC	56	51	-0.69 (1.111)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	121	0.12 (0.411)	0.26 (-0.92, 1.44)	0.670	0.038	0.0387 (0.12811)	(-0.2130, 0.2904)	0.763
	ABC/DTG/3TC	145	122	-0.13 (0.440)						
35-<50	Q4W IM	107	93	-0.82 (0.468)	-1.49 (-2.83, -0.16)	0.028	0.038	-0.2001 (0.14468)	(-0.4844, 0.0842)	0.167
	ABC/DTG/3TC	109	98	0.68 (0.491)						
>=50	Q4W IM	33	26	-0.64 (0.879)	2.93 (0.45, 5.41)	0.021	0.038	0.2098 (0.26975)	(-0.3202, 0.7398)	0.437
	ABC/DTG/3TC	29	29	-3.57 (0.914)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	-0.99 (0.629)	0.56 (-1.23, 2.36)	0.538	0.380	0.0558 (0.19229)	(-0.3220, 0.4336)	0.772
	ABC/DTG/3TC	64	56	-1.56 (0.670)						
Male	Q4W IM	220	188	-0.14 (0.330)	-0.31 (-1.26, 0.64)	0.522	0.380	-0.0582 (0.10233)	(-0.2593, 0.1429)	0.570
	ABC/DTG/3TC	219	193	0.17 (0.355)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	182	-0.51 (0.334)	-0.41 (-1.38, 0.56)	0.405	0.026	-0.0757 (0.10427)	(-0.2806, 0.1292)	0.468
	ABC/DTG/3TC	201	185	-0.10 (0.361)						
Non-White	Q4W IM	67	58	0.25 (0.596)	0.77 (-0.91, 2.45)	0.368	0.026	0.0819 (0.18103)	(-0.2738, 0.4376)	0.651
	ABC/DTG/3TC	80	64	-0.52 (0.614)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	38	-0.51 (0.745)	-0.63 (-2.62, 1.36)	0.534	0.130	-0.0571 (0.21397)	(-0.4775, 0.3634)	0.790
	ABC/DTG/3TC	62	51	0.12 (0.692)						
Europe	Q4W IM	213	181	-0.26 (0.344)	-0.11 (-1.10, 0.88)	0.832	0.130	-0.0194 (0.10632)	(-0.2283, 0.1895)	0.855
	ABC/DTG/3TC	192	172	-0.15 (0.381)						
Rest of World	Q4W IM	23	21	-0.51 (1.070)	0.75 (-1.98, 3.47)	0.590	0.130	0.0495 (0.29294)	(-0.5261, 0.6251)	0.866
	ABC/DTG/3TC	29	26	-1.26 (1.038)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

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Table 6.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at Week 48
 by Subgroup - MMRM - FLAIR

Domain: Physical Component Score
 Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	192	-0.18 (0.326)	0.07 (-0.87, 1.01)	0.888	0.276	0.0128 (0.10113)	(-0.1859, 0.2115)	0.899
	ABC/DTG/3TC	227	198	-0.25 (0.349)						
>=100,000	Q4W IM	56	48	-0.93 (0.651)	-0.85 (-2.72, 1.02)	0.371	0.276	-0.0813 (0.20081)	(-0.4759, 0.3133)	0.686
	ABC/DTG/3TC	56	51	-0.08 (0.691)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35-<50, >=50 years if subgroup = age), gender at birth (female, male), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF-12 scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.04

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

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	259	83.904	17.0467	87.500	75.000	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	276	85.122	15.8789	87.500	75.000	100.000	18.75	100.00	
				Week 48	263	85.694	15.8172	87.500	75.000	100.000	12.50	100.00	
		W48 CFB	241	1.193	14.3615	0.000	-6.250	6.250	-43.75	68.75			
		ABC/DTG/3TC	283	Maintenance	267	84.761	17.3156	87.500	75.000	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	270	83.889	17.8325	87.500	75.000	100.000	6.25	100.00	
Week 48	266			84.821	17.1836	90.625	75.000	100.000	18.75	100.00			
W48 CFB	251	0.249	14.8829	0.000	-6.250	6.250	-56.25	68.75					
Age (years) <35	Q4W IM	143	Maintenance	130	82.981	16.7274	87.500	75.000	100.000	31.25	100.00		
			BL (Day 1)										
			Week 24	137	85.949	15.7126	87.500	75.000	100.000	25.00	100.00		
			Week 48	133	85.808	15.7688	87.500	75.000	100.000	37.50	100.00		
		W48 CFB	122	2.049	14.1577	0.000	-6.250	12.500	-37.50	68.75			
		ABC/DTG/3TC	145	Maintenance	134	84.795	17.1626	90.625	75.000	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	139	83.633	17.7957	87.500	68.750	100.000	12.50	100.00	
Week 48	133			86.278	16.0724	93.750	75.000	100.000	31.25	100.00			
W48 CFB	123	1.778	16.0150	0.000	-6.250	12.500	-56.25	68.75					

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

PPD

09OCT2019 13:35

Table 6.04

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

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	85.038	16.5316	87.500	81.250	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	106	85.318	14.1485	87.500	75.000	100.000	43.75	100.00	
				Week 48	101	85.520	14.6290	87.500	75.000	100.000	31.25	100.00	
		W48 CFB	93	0.336	14.0471	0.000	-6.250	6.250	-43.75	56.25			
		ABC/DTG/3TC	109	Maintenance	104	86.178	16.4710	87.500	81.250	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	102	85.294	16.7716	87.500	75.000	100.000	6.25	100.00	
	Week 48			104	84.916	17.4968	93.750	75.000	100.000	18.75	100.00		
	W48 CFB	99	-1.073	12.9707	0.000	-6.250	6.250	-43.75	43.75				
	>=50	Q4W IM	33	Maintenance	30	84.167	20.2179	87.500	75.000	100.000	12.50	100.00	
				BL (Day 1)									
				Week 24	33	81.061	20.9914	87.500	75.000	93.750	18.75	100.00	
				Week 48	29	85.776	20.1069	93.750	81.250	100.000	12.50	100.00	
W48 CFB		26	0.240	16.6284	0.000	-6.250	12.500	-37.50	43.75				
ABC/DTG/3TC		29	Maintenance	29	79.526	20.3825	87.500	68.750	93.750	31.25	100.00		
	BL (Day 1)												
Week 24	29	80.172	21.3958	87.500	68.750	100.000	18.75	100.00					
Week 48	29	77.802	19.7350	81.250	68.750	93.750	31.25	100.00					
W48 CFB	29	-1.724	15.8375	0.000	-12.500	6.250	-31.25	43.75					

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	85.826	16.9596	87.500	81.250	100.000	31.25	100.00	
				BL (Day 1)									
				Week 24	61	85.861	17.5632	93.750	75.000	100.000	25.00	100.00	
		Week 48	59	86.335	14.9295	93.750	75.000	100.000	37.50	100.00			
		W48 CFB	52	0.721	14.9884	0.000	-6.250	9.375	-37.50	68.75			
		ABC/DTG/3TC	64	Maintenance	59	85.911	15.6398	87.500	75.000	100.000	31.25	100.00	
	BL (Day 1)												
	Week 24	61		84.939	17.2065	87.500	75.000	100.000	31.25	100.00			
	Week 48	61	85.758	19.2344	93.750	75.000	100.000	31.25	100.00				
	W48 CFB	56	0.446	16.7645	0.000	-9.375	6.250	-56.25	43.75				
	Male	Q4W IM	220	Maintenance	203	83.374	17.0742	87.500	75.000	100.000	0.00	100.00	
				BL (Day 1)									
Week 24				215	84.913	15.4053	87.500	75.000	100.000	18.75	100.00		
Week 48		204	85.509	16.0954	87.500	75.000	100.000	12.50	100.00				
W48 CFB		189	1.323	14.2225	0.000	-6.250	6.250	-43.75	56.25				
ABC/DTG/3TC		219	Maintenance	208	84.435	17.7840	87.500	75.000	100.000	0.00	100.00		
BL (Day 1)													
Week 24	209		83.583	18.0399	87.500	75.000	100.000	6.25	100.00				
Week 48	205	84.543	16.5655	87.500	75.000	100.000	18.75	100.00					
W48 CFB	195	0.192	14.3438	0.000	-6.250	6.250	-37.50	68.75					

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

PPD

Table 6.04

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

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	199	83.448	16.7457	87.500	75.000	93.750	0.00	100.00	
				BL (Day 1)									
				Week 24	210	84.940	15.3385	87.500	75.000	100.000	18.75	100.00	
				Week 48	198	85.795	15.2397	87.500	75.000	100.000	12.50	100.00	
		W48 CFB	183	1.981	15.1940	0.000	-6.250	12.500	-43.75	68.75			
		ABC/DTG/3TC	201	Maintenance	192	85.872	14.6190	87.500	75.000	100.000	31.25	100.00	
				BL (Day 1)									
				Week 24	194	84.729	16.2325	87.500	75.000	100.000	18.75	100.00	
	Week 48			193	84.942	16.8085	87.500	75.000	100.000	31.25	100.00		
	W48 CFB	185	-0.574	13.6328	0.000	-6.250	6.250	-37.50	43.75				
	Non-White	Q4W IM	67	Maintenance	60	85.417	18.0728	93.750	78.125	100.000	31.25	100.00	
				BL (Day 1)									
				Week 24	66	85.701	17.6015	93.750	75.000	100.000	25.00	100.00	
				Week 48	65	85.385	17.5834	93.750	75.000	100.000	31.25	100.00	
W48 CFB		58	-1.293	11.0916	0.000	-6.250	0.000	-37.50	37.50				
ABC/DTG/3TC		80	Maintenance	73	81.678	22.9481	87.500	75.000	100.000	0.00	100.00		
			BL (Day 1)										
			Week 24	74	81.419	21.5260	87.500	68.750	100.000	6.25	100.00		
	Week 48		71	84.155	18.3843	87.500	75.000	100.000	18.75	100.00			
W48 CFB	64	2.441	18.1148	0.000	-3.125	12.500	-56.25	68.75					

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

PPD

09OCT2019 13:35

Table 6.04

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

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	81.875	17.3805	87.500	75.000	93.750	31.25	100.00	
				BL (Day 1)									
				Week 24	46	81.114	18.5166	87.500	68.750	100.000	25.00	100.00	
				Week 48	45	82.361	17.6419	87.500	75.000	100.000	37.50	100.00	
		W48 CFB	38	-1.480	11.2963	0.000	-6.250	6.250	-37.50	25.00			
		ABC/DTG/3TC	62	84.698	17.8002	87.500	75.000	100.000	18.75	100.00			
	Europe	Q4W IM	213	Maintenance	197	84.105	16.5653	87.500	75.000	93.750	0.00	100.00	
				BL (Day 1)									
				Week 24	208	85.637	15.3187	87.500	75.000	100.000	18.75	100.00	
				Week 48	196	86.416	15.0194	87.500	75.000	100.000	12.50	100.00	
		W48 CFB	182	1.957	15.4437	0.000	-6.250	12.500	-43.75	68.75			
		ABC/DTG/3TC	192	85.852	14.8320	87.500	75.000	100.000	31.25	100.00			
				Maintenance	182	85.852	14.8320	87.500	75.000	100.000	31.25	100.00	
				BL (Day 1)									
				Week 24	182	84.375	16.1697	87.500	75.000	100.000	18.75	100.00	
				Week 48	181	84.116	16.7377	87.500	75.000	100.000	31.25	100.00	
W48 CFB	172	-0.945	13.9187	0.000	-6.250	6.250	-43.75	43.75					

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	23	Maintenance	22	85.795	20.8793	100.000	62.500	100.000	31.25	100.00	
				BL (Day 1)									
				Week 24	22	88.636	14.2569	96.875	75.000	100.000	62.50	100.00	
				Week 48	22	86.080	18.5938	93.750	75.000	100.000	31.25	100.00	
		W48 CFB	21	-0.595	7.6303	0.000	-6.250	0.000	-18.75	12.50			
		ABC/DTG/3TC	29	77.546	27.9110	87.500	68.750	100.000	0.00	100.00			
		ABC/DTG/3TC	29	Maintenance	27	77.546	27.9110	87.500	68.750	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	29	76.509	24.4730	75.000	56.250	100.000	6.25	100.00	
				Week 48	28	81.250	23.2613	96.875	68.750	100.000	18.75	100.00	
		W48 CFB	26	2.885	22.7919	0.000	0.000	12.500	-56.25	68.75			
		Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance	207	83.484	17.4594	87.500	75.000	100.000	0.00
BL (Day 1)													
Week 24	221	85.379				15.8313	87.500	75.000	100.000	18.75	100.00		
Week 48	212	85.908				16.4419	93.750	75.000	100.000	12.50	100.00		
W48 CFB	193	1.943				15.1580	0.000	-6.250	6.250	-43.75	68.75		
ABC/DTG/3TC	227	84.346				17.2657	87.500	75.000	100.000	0.00	100.00		
	ABC/DTG/3TC	227		Maintenance	214	84.346	17.2657	87.500	75.000	100.000	0.00	100.00	
				BL (Day 1)									
				Week 24	217	83.410	18.0075	87.500	75.000	100.000	6.25	100.00	
				Week 48	212	84.287	17.7245	90.625	75.000	100.000	18.75	100.00	
	W48 CFB	200		0.594	15.5838	0.000	-6.250	6.250	-56.25	68.75			

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

PPD

09OCT2019 13:35

Table 6.04

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

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance BL (Day 1)	52	85.577	15.3362	90.625	75.000	100.000	50.00	100.00
				Week 24	55	84.091	16.1741	87.500	75.000	100.000	31.25	100.00
				Week 48	51	84.804	13.0057	87.500	75.000	93.750	43.75	100.00
				W48 CFB	48	-1.823	10.1484	0.000	-9.375	0.000	-18.75	25.00
		ABC/DTG/3TC	56	Maintenance BL (Day 1)	53	86.439	17.5812	93.750	81.250	100.000	18.75	100.00
				Week 24	53	85.849	17.1230	93.750	75.000	100.000	43.75	100.00
				Week 48	54	86.921	14.8334	90.625	75.000	100.000	50.00	100.00
				W48 CFB	51	-1.103	11.7730	0.000	-6.250	6.250	-31.25	37.50

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

PPD

Table 6.04

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

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	259	88.9	13.34	95.0	80.0	100.0	30	100	
				BL (Day 1)									
				Week 24	276	92.0	11.55	95.0	87.5	100.0	35	100	
				Week 48	263	90.7	14.58	95.0	85.0	100.0	0	100	
		ABC/DTG/3TC	283	W48 CFB	241	1.5	17.14	0.0	-5.0	10.0	-85	65	
				Maintenance	267	87.4	16.54	90.0	80.0	100.0	0	100	
				BL (Day 1)									
				Week 24	270	89.2	15.27	95.0	85.0	100.0	0	100	
Age (years) <35		Q4W IM	143	Week 48	266	89.3	13.63	95.0	80.0	100.0	35	100	
				W48 CFB	251	2.0	16.64	0.0	-5.0	10.0	-55	100	
				Maintenance	130	87.8	13.60	90.0	80.0	100.0	30	100	
				BL (Day 1)									
		ABC/DTG/3TC	145	Week 24	137	92.8	9.01	95.0	85.0	100.0	60	100	
				Week 48	133	90.6	14.69	95.0	85.0	100.0	0	100	
				W48 CFB	122	1.9	18.20	0.0	-5.0	10.0	-85	65	
				Maintenance	134	85.8	17.13	90.0	80.0	100.0	0	100	
		BL (Day 1)											
		Week 24	139	87.0	16.45	95.0	80.0	100.0	10	100			
		Week 48	133	88.0	14.01	95.0	80.0	100.0	35	100			
		W48 CFB	123	1.8	17.65	0.0	-5.0	10.0	-55	65			

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

PPD

09OCT2019 13:35

Table 6.04

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

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	89.7	12.73	95.0	80.0	100.0	50	100	
				BL (Day 1)									
				Week 24	106	92.4	11.96	100.0	90.0	100.0	50	100	
				Week 48	101	90.7	13.33	95.0	85.0	100.0	40	100	
		W48 CFB	93	1.4	14.51	0.0	-5.0	10.0	-60	35			
		ABC/DTG/3TC	109	Maintenance	104	88.7	16.37	95.0	80.0	100.0	0	100	
	BL (Day 1)												
	>=50	Q4W IM	33	Maintenance	30	90.8	14.21	100.0	85.0	100.0	40	100	
				BL (Day 1)									
				Week 24	33	87.4	17.55	95.0	80.0	100.0	35	100	
				Week 48	29	90.7	18.36	100.0	90.0	100.0	10	100	
		W48 CFB	26	0.0	20.98	0.0	-5.0	5.0	-70	40			
ABC/DTG/3TC		29	Maintenance	29	90.5	13.85	95.0	90.0	100.0	40	100		
	BL (Day 1)												
				Week 24	29	92.4	10.74	95.0	90.0	100.0	55	100	
				Week 48	29	87.8	16.45	95.0	80.0	100.0	35	100	
				W48 CFB	29	-2.8	10.74	0.0	-10.0	5.0	-35	20	

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

PPD

Table 6.04

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

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	89.4	14.24	95.0	80.0	100.0	40	100	
				BL (Day 1)									
				Week 24	61	91.6	13.25	100.0	85.0	100.0	35	100	
				Week 48	59	89.2	19.87	95.0	85.0	100.0	0	100	
		W48 CFB	52	-0.3	21.97	0.0	-5.0	7.5	-85	40			
		ABC/DTG/3TC	64	Maintenance	59	87.7	17.89	90.0	80.0	100.0	0	100	
	BL (Day 1)												
	Male	Q4W IM	220	Maintenance	203	88.8	13.11	95.0	80.0	100.0	30	100	
				BL (Day 1)									
				Week 24	215	92.1	11.06	95.0	90.0	100.0	50	100	
				Week 48	204	91.1	12.68	95.0	85.0	100.0	15	100	
		W48 CFB	189	2.0	15.59	0.0	-5.0	10.0	-80	65			
ABC/DTG/3TC		219	Maintenance	208	87.4	16.18	90.0	80.0	100.0	0	100		
	BL (Day 1)												
				Week 24	209	89.2	14.12	95.0	80.0	100.0	10	100	
				Week 48	205	89.4	12.56	95.0	80.0	100.0	35	100	
				W48 CFB	195	2.0	16.35	0.0	-5.0	10.0	-55	100	

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

PPD

09OCT2019 13:35

Table 6.04

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

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	199	88.3	14.16	95.0	80.0	100.0	30	100	
				BL (Day 1)									
				Week 24	210	91.5	12.13	95.0	85.0	100.0	35	100	
				Week 48	198	90.5	14.78	95.0	85.0	100.0	0	100	
		W48 CFB	183	1.6	17.50	0.0	-5.0	10.0	-85	65			
		ABC/DTG/3TC	201	87.6	16.11	92.5	80.0	100.0	0	100			
	Non-White	Q4W IM	67	Maintenance	60	90.9	9.98	95.0	85.0	100.0	60	100	
				BL (Day 1)									
				Week 24	66	93.6	9.39	100.0	90.0	100.0	60	100	
				Week 48	65	91.3	14.04	95.0	90.0	100.0	15	100	
		W48 CFB	58	1.0	16.11	0.0	-5.0	5.0	-80	35			
		ABC/DTG/3TC	80	86.8	17.92	90.0	80.0	100.0	0	100			
				Maintenance	73	86.2	19.79	95.0	80.0	100.0	0	100	
				BL (Day 1)									
				Week 24	74	87.9	14.94	95.0	80.0	100.0	50	100	
				Week 48	71	87.9	14.94	95.0	80.0	100.0	50	100	
				W48 CFB	64	1.3	18.63	0.0	-7.5	7.5	-40	65	

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

PPD

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	90.4	11.17	95.0	85.0	100.0	60	100	
				BL (Day 1)									
				Week 24	46	94.0	9.35	100.0	90.0	100.0	60	100	
				Week 48	45	92.3	10.15	100.0	85.0	100.0	60	100	
		W48 CFB	38	1.6	14.19	0.0	-5.0	5.0	-40	35			
		ABC/DTG/3TC	62	Maintenance	58	89.1	14.37	95.0	80.0	100.0	35	100	
	BL (Day 1)												
	Europe	Q4W IM	213	Maintenance	197	88.2	14.06	95.0	80.0	100.0	30	100	
				BL (Day 1)									
				Week 24	208	91.3	12.23	95.0	85.0	100.0	35	100	
				Week 48	196	90.0	15.55	95.0	85.0	100.0	0	100	
		W48 CFB	182	1.3	18.34	0.0	-5.0	10.0	-85	65			
ABC/DTG/3TC		192	Maintenance	182	87.1	16.77	90.0	80.0	100.0	0	100		
	BL (Day 1)												
				Week 24	182	89.5	13.80	95.0	85.0	100.0	10	100	
				Week 48	181	88.8	13.95	95.0	80.0	100.0	35	100	
				W48 CFB	172	1.8	17.28	0.0	-5.0	5.0	-55	100	

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	23	Maintenance	22	92.7	9.22	97.5	90.0	100.0	70	100	
				BL (Day 1)									
				Week 24	22	93.9	8.30	95.0	90.0	100.0	70	100	
				Week 48	22	93.2	13.23	97.5	95.0	100.0	40	100	
		ABC/DTG/3TC	29	Maintenance	27	86.5	19.50	90.0	80.0	100.0	15	100	
				BL (Day 1)									
				Week 24	29	84.8	24.29	95.0	80.0	100.0	0	100	
				Week 48	28	90.0	15.21	100.0	80.0	100.0	55	100	
		W48 CFB	21	W48 CFB	21	2.9	10.32	0.0	-5.0	5.0	-20	20	
				W48 CFB	26	4.4	18.94	0.0	0.0	10.0	-40	50	
				W48 CFB	26	4.4	18.94	0.0	0.0	10.0	-40	50	
				W48 CFB	26	4.4	18.94	0.0	0.0	10.0	-40	50	
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance	207	88.9	13.32	95.0	80.0	100.0	30	100	
				BL (Day 1)									
				Week 24	221	92.0	11.14	95.0	85.0	100.0	35	100	
				Week 48	212	90.3	15.54	95.0	85.0	100.0	0	100	
		ABC/DTG/3TC	227	Maintenance	214	87.5	16.67	90.0	80.0	100.0	0	100	
				BL (Day 1)									
				Week 24	217	88.8	14.77	95.0	80.0	100.0	0	100	
				Week 48	212	89.2	13.71	95.0	80.0	100.0	35	100	
		W48 CFB	200	W48 CFB	200	1.9	16.94	0.0	-5.0	7.5	-55	100	
				W48 CFB	200	1.9	16.94	0.0	-5.0	7.5	-55	100	
				W48 CFB	200	1.9	16.94	0.0	-5.0	7.5	-55	100	
				W48 CFB	200	1.9	16.94	0.0	-5.0	7.5	-55	100	

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance BL (Day 1)	52	89.0	13.54	95.0	80.0	100.0	50	100
				Week 24	55	92.0	13.18	100.0	90.0	100.0	50	100
				Week 48	51	92.3	9.61	95.0	85.0	100.0	65	100
				W48 CFB	48	3.8	14.79	0.0	-5.0	10.0	-25	35
	ABC/DTG/3TC		56	Maintenance BL (Day 1)	53	87.4	16.16	95.0	80.0	100.0	35	100
				Week 24	53	91.0	17.22	95.0	90.0	100.0	10	100
				Week 48	54	89.5	13.43	95.0	85.0	100.0	55	100
				W48 CFB	51	2.1	15.59	0.0	-5.0	10.0	-35	50

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

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Table 6.04

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

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	259	57.5	30.91	60.0	30.0	85.0	0	100	
				BL (Day 1)									
				Week 24	276	57.6	31.39	60.0	35.0	85.0	0	100	
				Week 48	263	55.4	31.94	55.0	30.0	85.0	0	100	
		ABC/DTG/3TC	283	W48 CFB	241	-3.5	25.61	0.0	-20.0	10.0	-80	80	
				Maintenance	267	55.7	31.15	60.0	30.0	80.0	0	100	
				BL (Day 1)									
				Week 24	270	57.1	32.23	60.0	30.0	85.0	0	100	
Age (years) <35		Q4W IM	143	Week 48	266	57.7	31.11	60.0	30.0	85.0	0	100	
				W48 CFB	251	1.8	26.04	0.0	-10.0	15.0	-100	90	
				Maintenance	130	56.2	31.42	57.5	30.0	85.0	0	100	
				BL (Day 1)									
		ABC/DTG/3TC	145	Week 24	137	60.0	31.42	60.0	40.0	90.0	0	100	
				Week 48	133	53.4	31.95	50.0	25.0	80.0	0	100	
				W48 CFB	122	-3.7	24.69	0.0	-20.0	10.0	-75	80	
				Maintenance	134	54.7	29.57	55.0	30.0	80.0	0	100	
		BL (Day 1)											
		Week 24	139	56.3	29.99	60.0	30.0	80.0	0	100			
		Week 48	133	59.8	29.07	60.0	40.0	85.0	0	100			
		W48 CFB	123	4.8	25.50	5.0	-10.0	20.0	-75	90			

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

PPD

Table 6.04

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

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	60.7	29.69	60.0	35.0	90.0	5	100	
				BL (Day 1)									
				Week 24	106	56.0	31.45	55.0	30.0	80.0	0	100	
				Week 48	101	57.4	32.25	60.0	30.0	85.0	0	100	
		W48 CFB	93	-4.2	25.09	-5.0	-20.0	10.0	-80	65			
		ABC/DTG/3TC	109	Maintenance	104	57.9	31.56	60.0	30.0	90.0	0	100	
	BL (Day 1)												
	>=50	Q4W IM	33	Maintenance	30	53.0	32.68	50.0	20.0	85.0	5	100	
				BL (Day 1)									
				Week 24	33	52.6	31.08	50.0	30.0	75.0	0	100	
				Week 48	29	57.2	31.30	55.0	30.0	90.0	10	100	
		W48 CFB	26	0.4	31.78	10.0	0.0	20.0	-80	45			
ABC/DTG/3TC		29	Maintenance	29	52.4	37.00	60.0	20.0	85.0	0	100		
			BL (Day 1)										
Week 24		29	54.3	34.66	55.0	20.0	85.0	0	100				
			Week 48	29	49.7	33.83	60.0	20.0	80.0	0	100		
W48 CFB		29	-2.8	22.90	0.0	-10.0	10.0	-55	55				

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

PPD

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	53.8	35.93	45.0	17.5	90.0	0	100	
				BL (Day 1)									
				Week 24	61	56.6	31.33	60.0	35.0	80.0	0	100	
				Week 48	59	49.8	31.09	50.0	20.0	70.0	0	100	
		W48 CFB	52	-4.3	26.64	5.0	-20.0	15.0	-80	45			
		ABC/DTG/3TC	64	Maintenance	59	54.3	34.26	60.0	20.0	85.0	0	100	
	BL (Day 1)												
	Male	Q4W IM	220	Maintenance	203	58.6	29.39	60.0	35.0	85.0	0	100	
				BL (Day 1)									
				Week 24	215	57.9	31.47	60.0	35.0	85.0	0	100	
				Week 48	204	57.0	32.07	57.5	30.0	85.0	0	100	
		W48 CFB	189	-3.2	25.38	0.0	-20.0	10.0	-80	80			
ABC/DTG/3TC		219	Maintenance	208	56.1	30.29	60.0	30.0	80.0	0	100		
	BL (Day 1)												
				Week 24	209	58.3	30.98	60.0	35.0	85.0	0	100	
				Week 48	205	57.0	30.88	60.0	35.0	85.0	0	100	
				W48 CFB	195	0.5	25.26	0.0	-15.0	15.0	-100	90	

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	199	55.4	31.20	60.0	25.0	85.0	0	100	
				BL (Day 1)									
				Week 24	210	56.2	31.76	55.0	30.0	80.0	0	100	
				Week 48	198	54.6	32.58	55.0	25.0	85.0	0	100	
		W48 CFB	183	-1.9	26.61	0.0	-20.0	15.0	-80	80			
		ABC/DTG/3TC	201	55.7	30.38	60.0	30.0	80.0	0	100			
	Non-White	Q4W IM	67	Maintenance	60	64.8	29.02	67.5	35.0	90.0	15	100	
				BL (Day 1)									
				Week 24	66	62.1	29.95	65.0	40.0	85.0	0	100	
				Week 48	65	57.8	30.01	55.0	35.0	85.0	0	100	
		W48 CFB	58	-8.4	21.65	-5.0	-20.0	5.0	-60	35			
		ABC/DTG/3TC	80	55.6	33.69	60.0	30.0	80.0	0	100			
				Maintenance	73	55.6	33.69	60.0	30.0	80.0	0	100	
				BL (Day 1)									
				Week 24	74	58.4	33.26	65.0	30.0	90.0	0	100	
				Week 48	71	59.6	32.86	60.0	35.0	90.0	0	100	
				W48 CFB	64	4.6	25.39	0.0	-10.0	20.0	-75	90	

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

PPD

09OCT2019 13:35

Table 6.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	64.8	27.90	67.5	42.5	90.0	10	100	
				BL (Day 1)									
				Week 24	46	63.3	25.82	65.0	45.0	85.0	10	100	
				Week 48	45	60.8	28.34	65.0	45.0	80.0	0	100	
		W48 CFB	38	-5.9	27.70	-2.5	-25.0	10.0	-60	65			
		ABC/DTG/3TC	62	Maintenance	58	54.5	28.76	52.5	30.0	80.0	0	100	
	BL (Day 1)												
	Europe	Q4W IM	213	Maintenance	197	54.7	31.06	55.0	25.0	85.0	0	100	
				BL (Day 1)									
				Week 24	208	54.7	32.41	55.0	25.0	80.0	0	100	
				Week 48	196	52.2	32.57	50.0	22.5	82.5	0	100	
		W48 CFB	182	-3.7	25.93	0.0	-20.0	10.0	-80	80			
ABC/DTG/3TC		192	Maintenance	182	53.9	31.51	55.0	25.0	80.0	0	100		
	BL (Day 1)												
				Week 24	182	55.2	32.90	55.0	25.0	85.0	0	100	
				Week 48	181	54.2	30.85	55.0	30.0	80.0	0	100	
				W48 CFB	172	0.3	26.21	0.0	-15.0	15.0	-100	90	

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

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Table 6.04

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

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	23	Maintenance BL (Day 1)	22	69.8	30.99	85.0	40.0	100.0	20	100	
				Week 24	22	73.6	26.38	77.5	60.0	100.0	0	100	
				Week 48	22	72.3	27.16	80.0	45.0	100.0	0	100	
				W48 CFB	21	2.9	17.58	0.0	-5.0	10.0	-30	35	
		ABC/DTG/3TC	29	Maintenance BL (Day 1)	27	70.6	30.83	80.0	70.0	90.0	0	100	
				Week 24	29	67.4	35.45	75.0	55.0	100.0	0	100	
	Week 48			28	74.3	31.61	90.0	50.0	100.0	0	100		
	W48 CFB			26	2.1	31.66	0.0	-10.0	20.0	-75	90		
	Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance BL (Day 1)	207	56.8	31.27	60.0	25.0	85.0	0	100
					Week 24	221	56.4	32.00	60.0	30.0	85.0	0	100
					Week 48	212	55.0	31.92	55.0	27.5	85.0	0	100
			ABC/DTG/3TC	227	W48 CFB	193	-3.3	25.73	0.0	-20.0	10.0	-80	80
Maintenance BL (Day 1)					214	55.2	31.32	60.0	30.0	80.0	0	100	
Week 24					217	55.8	31.85	55.0	30.0	80.0	0	100	
Week 48	212	58.1	31.07	60.0	30.0	85.0	0	100					
W48 CFB	200	3.3	26.80	0.0	-10.0	20.0	-100	90					

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

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Table 6.04

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

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance BL (Day 1)	52	60.7	29.54	62.5	32.5	90.0	10	100
				Week 24	55	62.6	28.49	65.0	40.0	90.0	0	100
				Week 48	51	57.2	32.24	55.0	30.0	90.0	0	100
				W48 CFB	48	-4.2	25.36	0.0	-22.5	10.0	-65	50
		ABC/DTG/3TC	56	Maintenance BL (Day 1)	53	57.7	30.67	60.0	30.0	85.0	0	100
				Week 24	53	62.4	33.55	70.0	30.0	95.0	0	100
				Week 48	54	56.2	31.52	50.0	35.0	90.0	0	100
				W48 CFB	51	-4.0	22.07	0.0	-20.0	15.0	-55	45

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

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Table 6.05

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

Domain: Life Satisfaction Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	241	0.95	0.803	0.69 (-1.63, 3.01)	0.558	0.0537 (0.09024)	(-0.1236, 0.2310)	0.552
ABC/DTG/3TC	283	249	0.26	0.863					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.05

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

Domain: HIV Medication Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	241	1.61	0.923	0.13 (-2.24, 2.50)	0.914	0.0101 (0.09021)	(-0.1672, 0.1874)	0.911
ABC/DTG/3TC	283	249	1.48	0.776					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.05
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - FLAIR

Domain: Disclosure Worries Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	241	-3.46	1.555	-4.88 (-9.13, -0.63)	0.024	-0.2046 (0.09046)	(-0.3823, -0.0268)	0.024
ABC/DTG/3TC	283	249	1.42	1.500					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	122	1.60 (1.138)	-0.16 (-3.44, 3.13)	0.926	0.984	-0.0085 (0.12783)	(-0.2597, 0.2427)	0.947
	ABC/DTG/3TC	145	122	1.76 (1.232)						
35-<50	Q4W IM	107	93	0.41 (1.302)	0.74 (-2.98, 4.47)	0.695	0.984	0.0361 (0.14454)	(-0.2479, 0.3201)	0.803
	ABC/DTG/3TC	109	98	-0.33 (1.380)						
>=50	Q4W IM	33	26	0.18 (2.437)	4.18 (-2.72, 11.09)	0.235	0.984	0.1092 (0.26968)	(-0.4207, 0.6391)	0.686
	ABC/DTG/3TC	29	29	-4.00 (2.559)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	1.67 (1.742)	0.35 (-4.60, 5.30)	0.889	0.772	0.0128 (0.19228)	(-0.3650, 0.3906)	0.947
	ABC/DTG/3TC	64	56	1.32 (1.836)						
Male	Q4W IM	220	189	0.75 (0.910)	0.79 (-1.84, 3.41)	0.556	0.772	0.0540 (0.10219)	(-0.1468, 0.2548)	0.597
	ABC/DTG/3TC	219	193	-0.03 (0.982)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	183	1.54 (0.922)	1.51 (-1.16, 4.19)	0.267	0.335	0.1021 (0.10415)	(-0.1026, 0.3067)	0.328
	ABC/DTG/3TC	201	185	0.03 (1.002)						
Non-White	Q4W IM	67	58	-0.87 (1.648)	-1.77 (-6.41, 2.87)	0.454	0.335	-0.0686 (0.18102)	(-0.4243, 0.2871)	0.705
	ABC/DTG/3TC	80	64	0.90 (1.700)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	38	-2.07 (2.055)	-4.57 (-10.05, 0.90)	0.102	0.034	-0.1520 (0.21402)	(-0.5725, 0.2685)	0.478
	ABC/DTG/3TC	62	51	2.51 (1.908)						
Europe	Q4W IM	213	182	1.65 (0.950)	1.97 (-0.76, 4.70)	0.157	0.034	0.1312 (0.10626)	(-0.0776, 0.3400)	0.217
	ABC/DTG/3TC	192	172	-0.32 (1.055)						
Rest of World	Q4W IM	23	21	0.50 (2.986)	0.81 (-6.71, 8.34)	0.832	0.034	0.0196 (0.29293)	(-0.5560, 0.5952)	0.947
	ABC/DTG/3TC	29	26	-0.31 (2.917)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	193	1.63 (0.898)	1.44 (-1.16, 4.03)	0.277	0.201	0.0998 (0.10104)	(-0.0988, 0.2983)	0.324
	ABC/DTG/3TC	227	198	0.20 (0.966)						
>=100,000	Q4W IM	56	48	-1.75 (1.801)	-2.27 (-7.44, 2.90)	0.389	0.201	-0.0793 (0.20080)	(-0.4739, 0.3152)	0.693
	ABC/DTG/3TC	56	51	0.52 (1.920)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	122	1.79 (1.304)	1.68 (-1.67, 5.03)	0.325	0.026	0.0923 (0.12786)	(-0.1589, 0.3436)	0.471
	ABC/DTG/3TC	145	122	0.11 (1.105)						
35-<50	Q4W IM	107	93	1.80 (1.493)	-2.26 (-6.06, 1.55)	0.244	0.026	-0.1099 (0.14457)	(-0.3940, 0.1742)	0.447
	ABC/DTG/3TC	109	98	4.06 (1.234)						
>=50	Q4W IM	33	26	0.46 (2.804)	1.69 (-5.39, 8.77)	0.640	0.026	0.0440 (0.26964)	(-0.4859, 0.5739)	0.870
	ABC/DTG/3TC	29	29	-1.23 (2.288)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	0.75 (1.994)	-1.22 (-6.29, 3.85)	0.637	0.394	-0.0445 (0.19227)	(-0.4224, 0.3333)	0.817
	ABC/DTG/3TC	64	56	1.96 (1.653)						
Male	Q4W IM	220	189	1.84 (1.043)	0.50 (-2.18, 3.19)	0.713	0.394	0.0344 (0.10217)	(-0.1664, 0.2352)	0.737
	ABC/DTG/3TC	219	193	1.34 (0.883)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	183	1.32 (1.059)	-0.73 (-3.46, 2.00)	0.600	0.070	-0.0491 (0.10410)	(-0.2536, 0.1555)	0.638
	ABC/DTG/3TC	201	185	2.05 (0.902)						
Non-White	Q4W IM	67	58	2.57 (1.892)	2.73 (-2.04, 7.51)	0.261	0.070	0.1065 (0.18102)	(-0.2493, 0.4622)	0.557
	ABC/DTG/3TC	80	64	-0.17 (1.530)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	38	3.10 (2.346)	1.40 (-4.29, 7.09)	0.630	0.508	0.0470 (0.21393)	(-0.3734, 0.4675)	0.826
	ABC/DTG/3TC	62	51	1.70 (1.724)						
Europe	Q4W IM	213	182	0.70 (1.081)	-0.49 (-3.27, 2.29)	0.729	0.508	-0.0324 (0.10617)	(-0.2410, 0.1763)	0.760
	ABC/DTG/3TC	192	172	1.19 (0.954)						
Rest of World	Q4W IM	23	21	6.69 (3.339)	3.70 (-4.08, 11.48)	0.351	0.508	0.0904 (0.29290)	(-0.4853, 0.6661)	0.758
	ABC/DTG/3TC	29	26	2.99 (2.646)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

Domain: HIV Medication Transformed Total Score
 Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	193	1.26 (1.032)	-0.15 (-2.80, 2.50)	0.912	0.864	-0.0103 (0.10099)	(-0.2088, 0.1882)	0.919
	ABC/DTG/3TC	227	198	1.41 (0.870)						
>=100,000	Q4W IM	56	48	3.01 (2.068)	1.23 (-4.07, 6.53)	0.648	0.864	0.0429 (0.20077)	(-0.3516, 0.4375)	0.831
	ABC/DTG/3TC	56	51	1.78 (1.728)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	122	-3.90 (2.205)	-7.77 (-13.80, -1.74)	0.012	0.724	-0.2305 (0.12805)	(-0.4821, 0.0211)	0.072
	ABC/DTG/3TC	145	122	3.87 (2.144)						
35-<50	Q4W IM	107	93	-3.39 (2.520)	-3.50 (-10.32, 3.33)	0.314	0.724	-0.0918 (0.14457)	(-0.3759, 0.1923)	0.526
	ABC/DTG/3TC	109	98	0.11 (2.393)						
>=50	Q4W IM	33	26	-1.55 (4.672)	2.87 (-9.73, 15.46)	0.655	0.724	0.0405 (0.26967)	(-0.4894, 0.5703)	0.881
	ABC/DTG/3TC	29	29	-4.42 (4.436)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	-5.18 (3.367)	-10.45 (-19.51, -1.40)	0.024	0.732	-0.2068 (0.19240)	(-0.5848, 0.1713)	0.283
	ABC/DTG/3TC	64	56	5.28 (3.187)						
Male	Q4W IM	220	189	-2.99 (1.758)	-3.28 (-8.09, 1.52)	0.180	0.732	-0.1218 (0.10225)	(-0.3227, 0.0792)	0.234
	ABC/DTG/3TC	219	193	0.29 (1.703)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	183	-2.90 (1.782)	-3.83 (-8.73, 1.06)	0.125	0.458	-0.1396 (0.10419)	(-0.3443, 0.0651)	0.181
	ABC/DTG/3TC	201	185	0.93 (1.744)						
Non-White	Q4W IM	67	58	-5.27 (3.207)	-8.09 (-16.66, 0.47)	0.064	0.458	-0.1693 (0.18109)	(-0.5251, 0.1865)	0.350
	ABC/DTG/3TC	80	64	2.82 (2.962)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	38	-1.57 (3.923)	-8.45 (-18.48, 1.58)	0.099	0.430	-0.1536 (0.21402)	(-0.5741, 0.2670)	0.473
	ABC/DTG/3TC	62	51	6.88 (3.310)						
Europe	Q4W IM	213	182	-5.57 (1.811)	-4.25 (-9.20, 0.69)	0.092	0.430	-0.1540 (0.10629)	(-0.3628, 0.0549)	0.148
	ABC/DTG/3TC	192	172	-1.32 (1.833)						
Rest of World	Q4W IM	23	21	11.27 (5.722)	2.03 (-11.71, 15.77)	0.771	0.430	0.0270 (0.29292)	(-0.5486, 0.6026)	0.927
	ABC/DTG/3TC	29	26	9.23 (5.121)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.06

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

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	193	-3.26 (1.742)	-5.84 (-10.59, -1.09)	0.016	0.544	-0.2190 (0.10124)	(-0.4180, -0.0201)	0.031
	ABC/DTG/3TC	227	198	2.58 (1.677)						
>=100,000	Q4W IM	56	48	-4.30 (3.488)	-1.20 (-10.67, 8.26)	0.803	0.544	-0.0227 (0.20079)	(-0.4172, 0.3718)	0.910
	ABC/DTG/3TC	56	51	-3.10 (3.323)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	283	Maintenance	259	59.3	7.37	61.0	56.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	273	59.6	7.57	62.0	55.0	66.0	17	66	
				Week 24	272	61.3	6.41	64.0	59.0	66.0	24	66	
				Week 44	261	61.4	5.83	64.0	59.0	66.0	31	66	
		W44 CFB	238	1.8	7.68	0.5	-2.0	4.0	-32	36			
		ABC/DTG/3TC	283	Maintenance	266	59.1	7.55	61.0	56.0	66.0	26	66	
				BL (Day 1)									
				Week 24	271	58.8	8.27	61.0	55.0	66.0	18	66	
				Week 44	263	59.8	7.07	62.0	56.0	66.0	27	66	
W44 CFB	247			1.0	6.99	0.0	-2.0	4.0	-27	25			
Age (years) <35		Q4W IM	143	Maintenance	130	59.1	6.94	60.5	55.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	137	59.9	7.22	62.0	56.0	66.0	24	66	
				Week 24	136	61.9	5.06	64.0	59.0	66.0	40	66	
				Week 44	133	61.6	5.55	64.0	59.0	66.0	31	66	
		W44 CFB	121	2.1	7.28	1.0	-1.0	6.0	-32	27			
		ABC/DTG/3TC	145	Maintenance	133	58.1	7.82	59.0	54.0	65.0	33	66	
				BL (Day 1)									
				Week 24	140	57.6	9.04	59.0	54.0	65.0	18	66	
				Week 44	133	59.0	7.36	61.0	55.0	66.0	27	66	
W44 CFB	122			0.9	7.37	0.0	-3.0	4.0	-27	20			

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35-<50	Q4W IM	107	Maintenance	99	59.8	7.38	62.0	56.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	104	59.0	7.76	61.0	55.0	65.5	17	66	
				Week 24	104	61.1	6.59	63.5	58.0	66.0	32	66	
				Week 44	99	61.3	6.05	64.0	59.0	66.0	37	66	
				W44 CFB	91	1.3	7.92	0.0	-2.0	4.0	-26	36	
		ABC/DTG/3TC	109	Maintenance	104	60.0	7.42	62.0	58.0	66.0	26	66	
				BL (Day 1)									
				Week 24	102	59.9	7.23	62.0	57.0	66.0	32	66	
				Week 44	101	60.8	6.55	63.0	57.0	66.0	36	66	
				W44 CFB	96	1.3	6.49	0.0	-2.0	4.5	-13	25	
	>=50	Q4W IM	33	Maintenance	30	58.3	9.09	61.5	54.0	66.0	34	66	
				BL (Day 1)									
Week 4B				32	60.4	8.44	64.5	58.0	66.0	35	66		
Week 24				32	59.6	9.96	65.0	57.0	66.0	24	66		
		ABC/DTG/3TC	29	Maintenance	29	60.1	6.25	62.0	55.0	66.0	44	66	
				BL (Day 1)									
				Week 24	29	60.6	7.09	64.0	58.0	66.0	36	66	
				Week 44	29	60.3	7.28	63.0	57.0	66.0	34	66	
			W44 CFB	29	0.2	7.15	0.0	-2.0	3.0	-17	17		

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Gender at Birth	Female	Q4W IM	63	Maintenance	56	61.4	6.50	65.0	58.5	66.0	34	66	
				BL (Day 1)									
				Week 4B	58	61.5	6.72	65.0	60.0	66.0	40	66	
				Week 24	60	62.3	5.84	65.0	60.0	66.0	40	66	
				Week 44	59	61.9	4.95	65.0	58.0	66.0	48	66	
		W44 CFB	52	-0.0	6.51	0.0	-3.0	1.0	-15	21			
		ABC/DTG/3TC	64	Maintenance	59	61.2	5.96	63.0	59.0	66.0	39	66	
				BL (Day 1)									
				Week 24	61	60.3	8.24	64.0	57.0	66.0	30	66	
				Week 44	60	60.9	6.79	64.0	58.0	66.0	34	66	
	W44 CFB			55	0.4	6.34	0.0	-3.0	3.0	-17	24		
	Male	Q4W IM	220	Maintenance	203	58.7	7.50	61.0	55.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	215	59.1	7.71	61.0	55.0	66.0	17	66	
Week 24				212	61.1	6.55	63.0	58.5	66.0	24	66		
Week 44				202	61.3	6.07	64.0	59.0	66.0	31	66		
W44 CFB		186	2.3	7.92	1.0	-1.0	6.0	-32	36				
ABC/DTG/3TC		219	Maintenance	207	58.5	7.85	60.0	55.0	65.0	26	66		
			BL (Day 1)										
			Week 24	210	58.4	8.25	61.0	54.0	65.0	18	66		
	Week 44		203	59.5	7.14	62.0	56.0	66.0	27	66			
W44 CFB	192	1.1	7.18	0.0	-2.0	5.0	-27	25					

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Race	White	Q4W IM	216	Maintenance	199	59.3	7.22	61.0	56.0	66.0	30	66	
				BL (Day 1)									
				Week 4B	210	59.5	7.60	62.0	55.0	66.0	17	66	
				Week 24	207	61.1	6.59	64.0	59.0	66.0	24	66	
				Week 44	195	61.1	5.99	63.0	58.0	66.0	31	66	
		W44 CFB	179	1.5	7.95	0.0	-2.0	4.0	-32	36			
		ABC/DTG/3TC	201	Maintenance	191	59.1	7.13	61.0	56.0	65.0	26	66	
	BL (Day 1)												
	Non-White	Q4W IM	67	Maintenance	60	59.2	7.90	62.0	56.5	65.0	36	66	
				BL (Day 1)									
				Week 4B	63	60.0	7.51	64.0	55.0	66.0	35	66	
				Week 24	65	62.1	5.80	64.0	61.0	66.0	37	66	
				Week 44	66	62.3	5.27	65.0	59.0	66.0	44	66	
		W44 CFB	59	2.7	6.75	1.0	-1.0	5.0	-8	27			
ABC/DTG/3TC		80	Maintenance	73	58.9	8.68	63.0	55.0	66.0	33	66		
	BL (Day 1)												
				Week 24	74	58.2	9.58	61.0	55.0	66.0	18	66	
				Week 44	68	59.6	7.06	62.0	55.0	66.0	39	66	
				W44 CFB	61	1.1	7.43	0.0	-3.0	3.0	-16	20	

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	North America	Q4W IM	47	Maintenance	40	60.8	5.83	62.0	57.5	65.5	44	66	
				BL (Day 1)									
				Week 4B	45	60.9	6.01	64.0	58.0	66.0	47	66	
				Week 24	46	63.0	4.60	64.0	62.0	66.0	40	66	
				Week 44	44	63.3	4.16	65.0	62.5	66.0	49	66	
	W44 CFB	37	2.1	6.23	1.0	0.0	4.0	-10	20				
	Europe	Q4W IM	213	Maintenance	197	59.1	7.34	61.0	56.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	205	59.5	7.60	62.0	55.0	66.0	17	66	
				Week 24	204	61.0	6.67	64.0	58.0	66.0	24	66	
				Week 44	195	61.1	5.99	63.0	58.0	66.0	31	66	
		W44 CFB	180	1.8	8.19	0.0	-2.0	5.0	-32	36			
		ABC/DTG/3TC	192	Maintenance	182	59.0	6.89	60.0	56.0	64.0	26	66	
				BL (Day 1)									
Week 24				183	58.6	8.07	61.0	55.0	66.0	22	66		
Week 44	177			59.4	7.27	62.0	56.0	66.0	27	66			
W44 CFB	168	0.9	6.90	0.0	-2.0	4.5	-27	25					

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	23	Maintenance	22	58.0	9.78	62.5	53.0	66.0	36	66	
				BL (Day 1)									
				Week 4B	23	58.2	9.70	63.0	48.0	66.0	35	66	
				Week 24	22	60.9	6.97	64.0	57.0	65.0	37	66	
				Week 44	22	60.4	6.68	64.5	55.0	65.0	44	66	
	W44 CFB	21	1.6	5.35	0.0	-2.0	5.0	-7	12				
	ABC/DTG/3TC	29	Maintenance	27	56.0	11.20	59.0	46.0	66.0	33	66		
			BL (Day 1)										
			Week 24	29	57.6	8.91	59.0	52.0	66.0	30	66		
			Week 44	28	58.8	7.51	60.0	54.5	66.0	39	66		
W44 CFB			26	2.7	8.18	0.0	-3.0	12.0	-12	20			
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	Q4W IM	227	Maintenance	207	59.5	7.16	61.0	56.0	66.0	30	66	
				BL (Day 1)									
				Week 4B	218	59.6	7.75	62.0	55.0	66.0	17	66	
				Week 24	217	61.5	6.25	64.0	59.0	66.0	24	66	
				Week 44	210	61.4	5.59	64.0	59.0	66.0	40	66	
	W44 CFB	190	1.7	6.56	1.0	-1.0	4.0	-20	27				
	ABC/DTG/3TC	227	Maintenance	213	58.8	7.70	60.0	56.0	65.0	26	66		
			BL (Day 1)										
			Week 24	218	58.4	8.49	61.0	54.0	66.0	18	66		
			Week 44	209	59.4	7.44	62.0	56.0	66.0	27	66		
W44 CFB			196	0.9	7.00	0.0	-2.0	4.0	-27	25			

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

PPD

25OCT2019 10:47

Table 6.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - FLAIR

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Induction BL (Week -20) HIV-1 RNA (c/mL)	>=100,000	Q4W IM	56	Maintenance	52	58.4	8.16	61.0	55.0	65.0	30	66	
				BL (Day 1)									
				Week 4B	55	59.7	6.83	61.0	55.0	66.0	35	66	
				Week 24	55	60.7	7.06	63.0	58.0	66.0	32	66	
				Week 44	51	61.3	6.78	64.0	59.0	66.0	31	66	
			W44 CFB	48	2.2	11.13	0.0	-2.0	5.5	-32	36		
		ABC/DTG/3TC	56	Maintenance	53	60.3	6.82	62.0	57.0	66.0	33	66	
	BL (Day 1)												
	Week 24			53	60.2	7.21	62.0	58.0	66.0	30	66		
	Week 44			54	61.4	5.18	63.5	57.0	66.0	47	66		
W44 CFB	51			1.1	7.02	0.0	-3.0	3.0	-13	20			

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

PPD

25OCT2019 10:47

Table 6.08

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

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	283	238	1.59	0.392	0.81 (-0.26, 1.88)	0.137	0.1455 (0.09099)	(-0.0334, 0.3243)	0.111
ABC/DTG/3TC	283	245	0.78	0.378					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years), race (white, non-white) and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - ABC/DTG/3TC.

Note: MMRM=Mixed Model Repeated Measures.

Table 6.09

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

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	143	121	2.11 (0.553)	1.94 (0.43, 3.46)	0.012	0.017	0.2468 (0.12862)	(-0.0060, 0.4996)	0.056
	ABC/DTG/3TC	145	121	0.16 (0.537)						
35-<50	Q4W IM	107	91	1.11 (0.636)	-0.52 (-2.24, 1.21)	0.556	0.017	-0.0575 (0.14643)	(-0.3453, 0.2304)	0.695
	ABC/DTG/3TC	109	95	1.63 (0.605)						
>=50	Q4W IM	33	26	0.97 (1.178)	0.33 (-2.83, 3.49)	0.837	0.017	0.0200 (0.26960)	(-0.5099, 0.5500)	0.941
	ABC/DTG/3TC	29	29	0.64 (1.105)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.09

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

Subgroup: Gender at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	63	52	1.16 (0.846)	-0.23 (-2.51, 2.05)	0.844	0.360	-0.0194 (0.19307)	(-0.3989, 0.3601)	0.920
	ABC/DTG/3TC	64	55	1.39 (0.805)						
Male	Q4W IM	220	186	1.71 (0.442)	1.11 (-0.10, 2.32)	0.073	0.360	0.1752 (0.10314)	(-0.0276, 0.3779)	0.090
	ABC/DTG/3TC	219	190	0.61 (0.430)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.09

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

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	216	179	1.22 (0.451)	0.35 (-0.88, 1.59)	0.573	0.139	0.0549 (0.10481)	(-0.1511, 0.2609)	0.601
	ABC/DTG/3TC	201	184	0.87 (0.437)						
Non-White	Q4W IM	67	59	2.74 (0.796)	2.20 (0.04, 4.35)	0.046	0.139	0.1970 (0.18240)	(-0.1615, 0.5555)	0.281
	ABC/DTG/3TC	80	61	0.54 (0.755)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction
 Score at Week 44 by Subgroup - MMRM - FLAIR

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

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	47	37	2.84 (1.005)	1.79 (-0.77, 4.34)	0.170	0.729	0.1390 (0.21560)	(-0.2848, 0.5629)	0.519
	ABC/DTG/3TC	62	51	1.05 (0.838)						
Europe	Q4W IM	213	180	1.47 (0.461)	0.74 (-0.52, 2.00)	0.248	0.729	0.1125 (0.10715)	(-0.0981, 0.3231)	0.294
	ABC/DTG/3TC	192	168	0.73 (0.466)						
Rest of World	Q4W IM	23	21	0.44 (1.437)	-0.09 (-3.57, 3.38)	0.958	0.729	-0.0053 (0.29284)	(-0.5811, 0.5704)	0.985
	ABC/DTG/3TC	29	26	0.53 (1.282)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Table 6.09

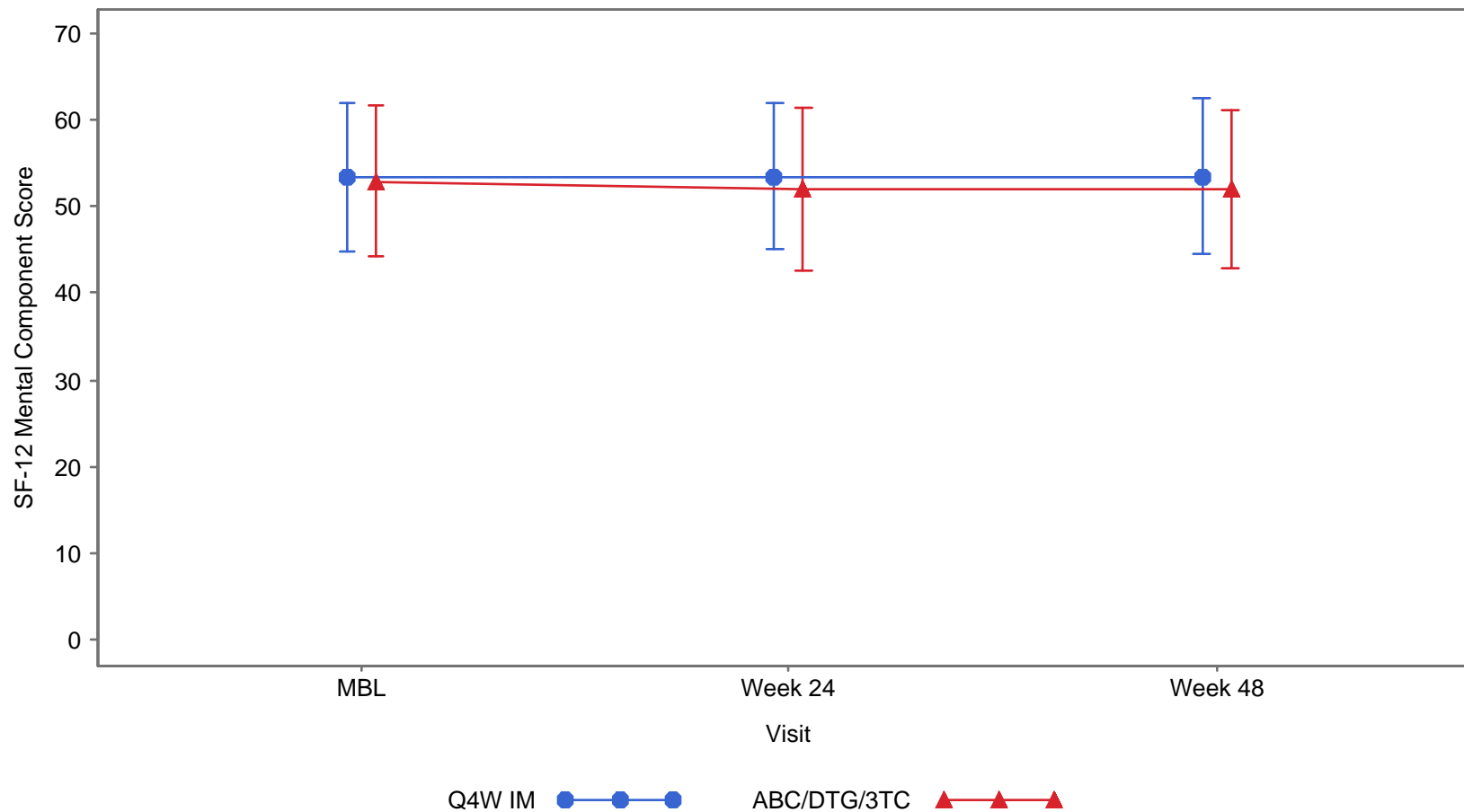
Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<100,000	Q4W IM	227	190	1.67 (0.439)	1.15 (-0.05, 2.36)	0.060	0.209	0.1842 (0.10208)	(-0.0165, 0.3848)	0.072
	ABC/DTG/3TC	227	194	0.52 (0.424)						
>=100,000	Q4W IM	56	48	1.27 (0.873)	-0.52 (-2.89, 1.86)	0.670	0.209	-0.0418 (0.20074)	(-0.4364, 0.3528)	0.835
	ABC/DTG/3TC	56	51	1.79 (0.833)						

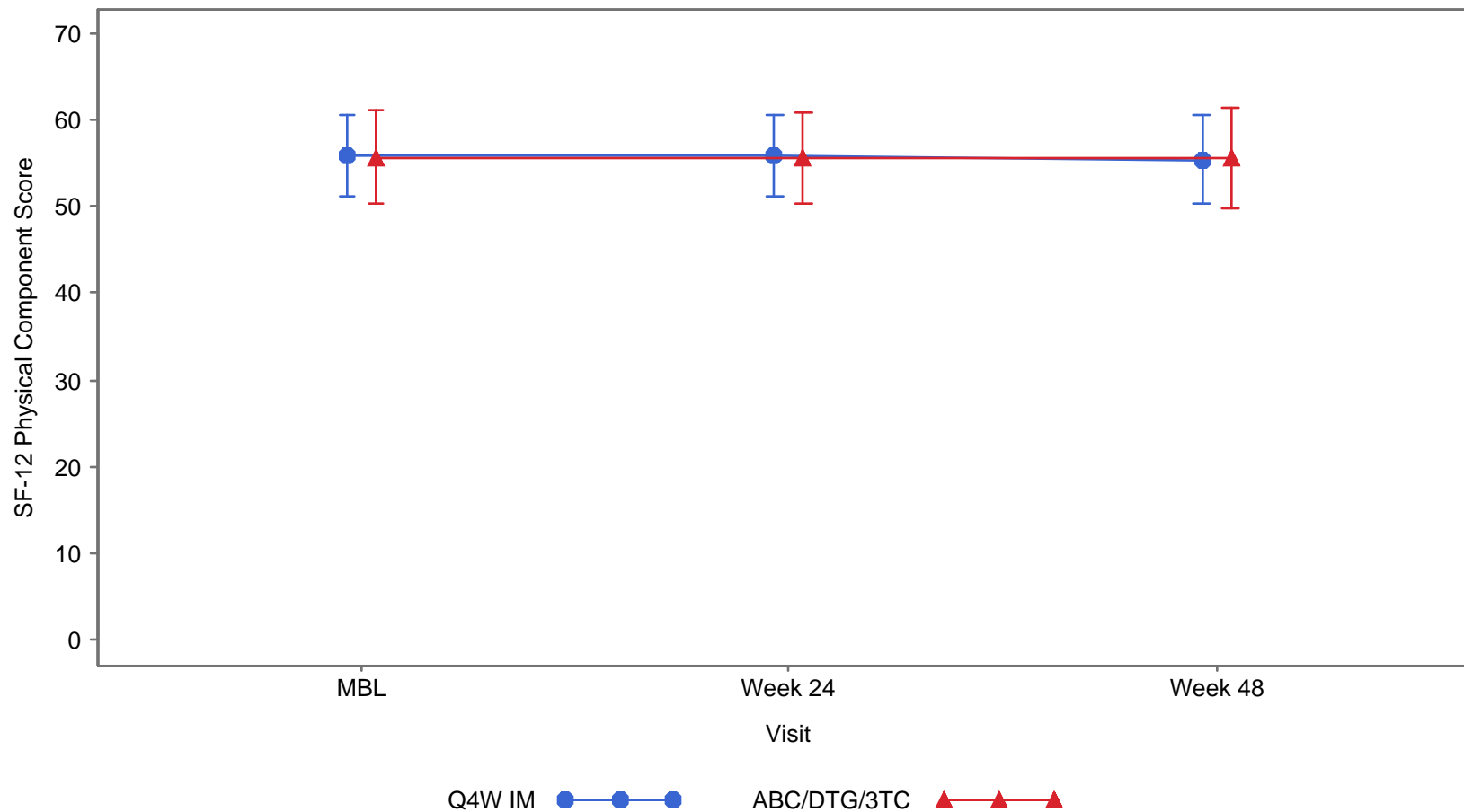
[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment* subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, gender at birth (female, male), age (<50, >=50 years; or <35, 35-<50, >= 50 years if subgroup = age), race (white, non-white), and Induction BL (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured. [2] Difference:= Q4W IM - ABC/DTG/3TC.
 Note: MMRM=Mixed Model Repeated Measures.

Figure 6.01
Line Plot of SF-12 - Mean MCS and PCS Scores Over Time (Maintenance Phase) - FLAIR



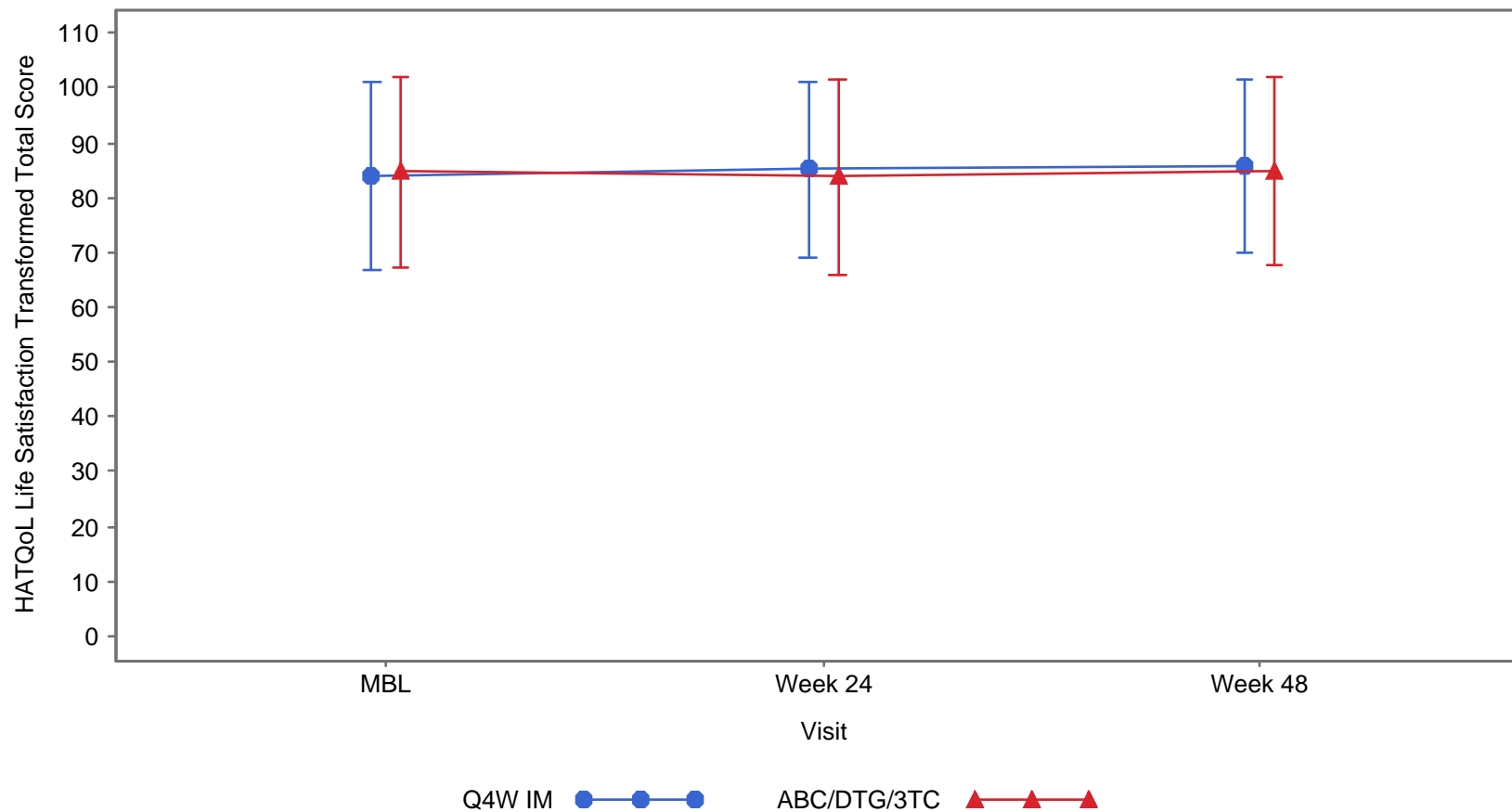
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.01
Line Plot of SF-12 - Mean MCS and PCS Scores Over Time (Maintenance Phase) - FLAIR



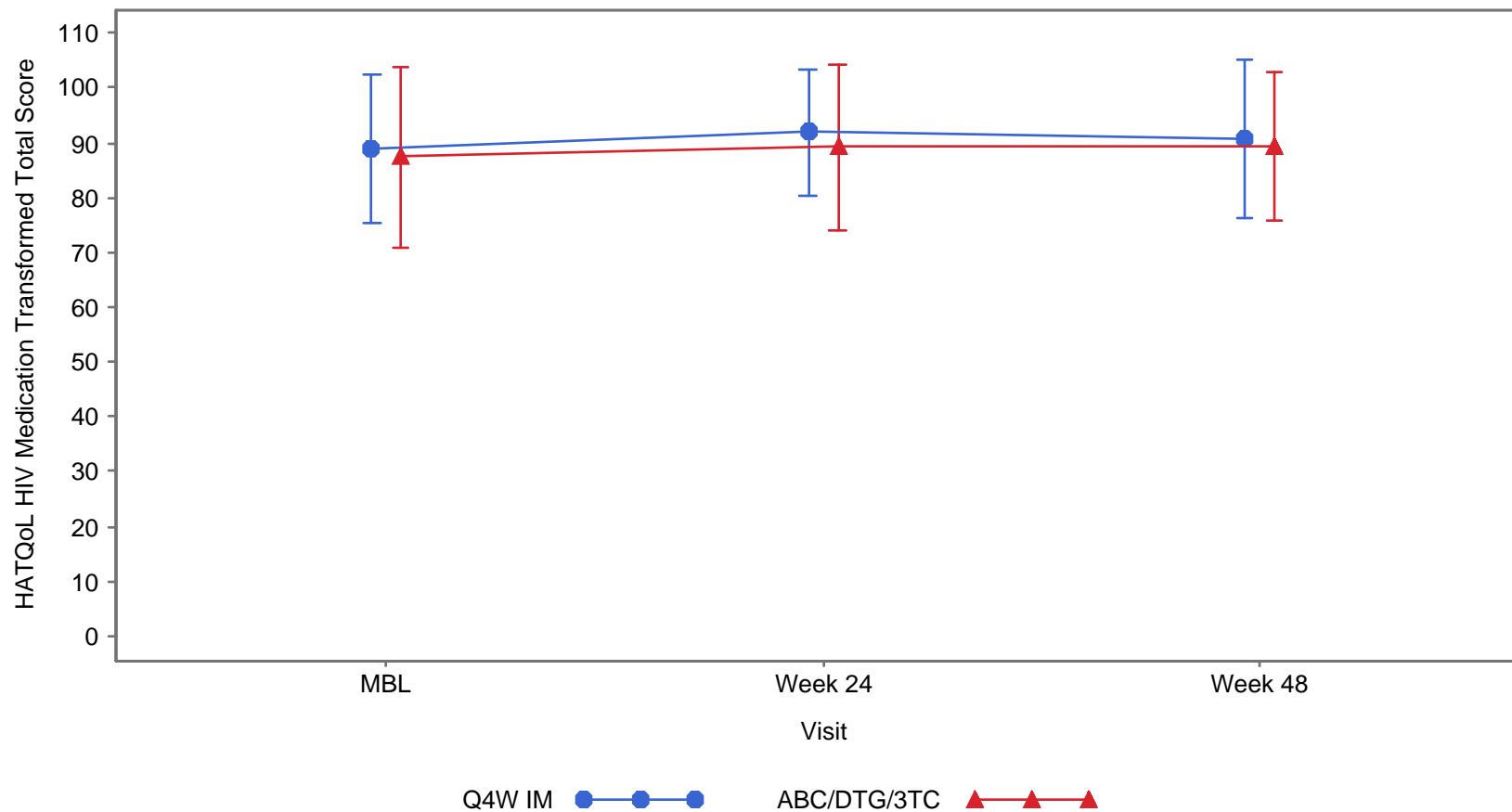
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - FLAIR



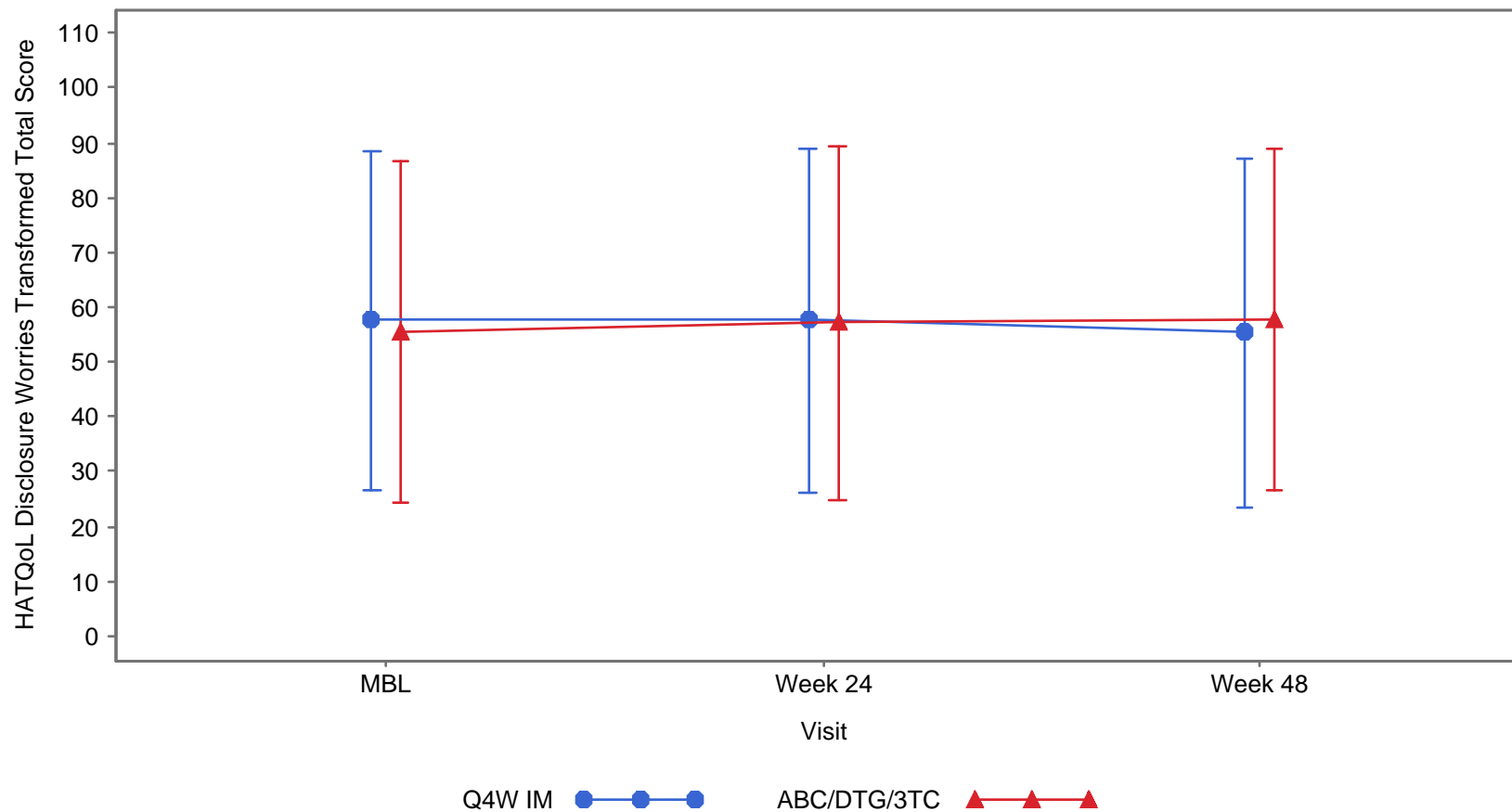
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - FLAIR



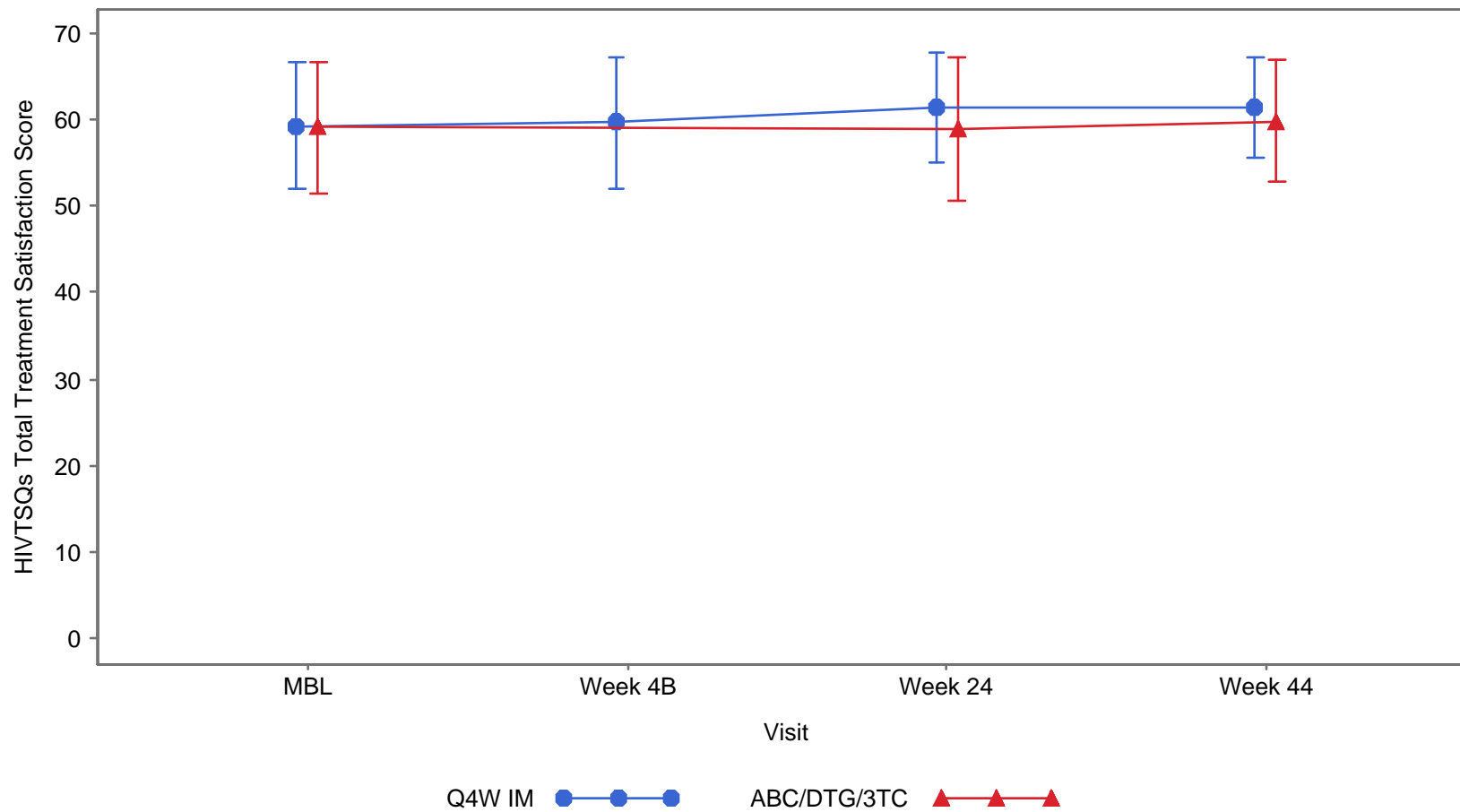
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - FLAIR



Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.03
Line Plot of HIVTSQs - Mean Total Treatment Satisfaction Score Over Time (Maintenance Phase) - FLAIR



Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	267 (94%)	225 (80%)	4.3017 (2.4056, 7.6921) /<.001	14.8410 (9.4226, 20.2593) /<.001	1.1867 (1.1112, 1.2672) /<.001
Max Grade 1	93 (33%)	119 (42%)	0.6746 (0.4790, 0.9500) /0.024	-9.1873 (-17.1261, -1.2484) /0.023	0.7815 (0.6300, 0.9694) /0.025
Max Grade 2	143 (51%)	95 (34%)	2.0214 (1.4396, 2.8381) /<.001	16.9611 (8.9485, 24.9737) /<.001	1.5053 (1.2319, 1.8392) /<.001
Max Grade 3	23 (8%)	10 (4%)	2.4150 (1.1276, 5.1721) /0.023	4.5936 (0.7515, 8.4358) /0.019	2.3000 (1.1152, 4.7436) /0.024
Max Grade 4	8 (3%)	1 (<1%)	8.2036 (1.0193, 66.0267) /0.048	2.4735 (0.4225, 4.5245) /0.018	8.0000 (1.0072, 63.5450) /0.049
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infestations and infections					
Any Event	196 (69%)	173 (61%)	1.4325 (1.0118, 2.0281) /0.043	8.1272 (0.3071, 15.9473) /0.042	1.1329 (1.0038, 1.2788) /0.043
Max Grade 1	132 (47%)	123 (43%)	1.1371 (0.8164, 1.5838) /0.447	3.1802 (-5.0135, 11.3739) /0.447	1.0732 (0.8944, 1.2876) /0.447
Max Grade 2	56 (20%)	48 (17%)	1.2078 (0.7884, 1.8502) /0.386	2.8269 (-3.5499, 9.2036) /0.385	1.1667 (0.8233, 1.6532) /0.386
Max Grade 3	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 4	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 5	0	0			
Max Grade NA	5 (2%)	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasopharyngitis Any Event	56 (20%)	48 (17%)	1.2078 (0.7884, 1.8502) /0.386	2.8269 (-3.5499, 9.2036) /0.385	1.1667 (0.8233, 1.6532) /0.386
Max Grade 1	50 (18%)	44 (16%)	1.1656 (0.7481, 1.8162) /0.498	2.1201 (-4.0092, 8.2495) /0.498	1.1364 (0.7848, 1.6453) /0.498
Max Grade 2	6 (2%)	4 (1%)	1.5108 (0.4217, 5.4123) /0.526	0.7067 (-1.4632, 2.8766) /0.523	1.5000 (0.4279, 5.2585) /0.526
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Upper respiratory tract infection					
Any Event	38 (13%)	28 (10%)	1.4125 (0.8409, 2.3728) /0.192	3.5336 (-1.7466, 8.8138) /0.190	1.3571 (0.8572, 2.1487) /0.193
Max Grade 1	32 (11%)	23 (8%)	1.4412 (0.8206, 2.5310) /0.203	3.1802 (-1.6930, 8.0535) /0.201	1.3913 (0.8356, 2.3165) /0.204
Max Grade 2	6 (2%)	5 (2%)	1.2043 (0.3633, 3.9922) /0.761	0.3534 (-1.9210, 2.6277) /0.761	1.2000 (0.3705, 3.8870) /0.761
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza					
Any Event	25 (9%)	20 (7%)	1.2742 (0.6906, 2.3511) /0.438	1.7668 (-2.6882, 6.2218) /0.437	1.2500 (0.7109, 2.1981) /0.438
Max Grade 1	18 (6%)	17 (6%)	1.0628 (0.5361, 2.1070) /0.861	0.3534 (-3.6151, 4.3218) /0.861	1.0588 (0.5572, 2.0122) /0.861
Max Grade 2	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	3 (1%)	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastroenteritis					
Any Event	15 (5%)	11 (4%)	1.3840 (0.6243, 3.0681) /0.424	1.4134 (-2.0340, 4.8608) /0.422	1.3636 (0.6375, 2.9169) /0.424
Max Grade 1	13 (5%)	9 (3%)	1.4658 (0.6164, 3.4861) /0.387	1.4134 (-1.7691, 4.5960) /0.384	1.4444 (0.6275, 3.3251) /0.387
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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05NOV2019 12:02

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory tract infection viral					
Any Event	13 (5%)	12 (4%)	1.0873 (0.4874, 2.4260) /0.838	0.3534 (-3.0320, 3.7387) /0.838	1.0833 (0.5030, 2.3330) /0.838
Max Grade 1	11 (4%)	7 (2%)	1.5945 (0.6091, 4.1741) /0.342	1.4134 (-1.4754, 4.3023) /0.338	1.5714 (0.6180, 3.9956) /0.342
Max Grade 2	2 (<1%)	4 (1%)	0.4964 (0.0902, 2.7323) /0.421	-0.7067 (-2.3931, 0.9797) /0.411	0.5000 (0.0923, 2.7080) /0.421
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	0	1 (<1%)			

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

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

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

PPD

05NOV2019 12:02

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis					
Any Event	15 (5%)	9 (3%)	1.7040 (0.7331, 3.9604) /0.215	2.1201 (-1.1954, 5.4357) /0.210	1.6667 (0.7416, 3.7458) /0.216
Max Grade 1	13 (5%)	9 (3%)	1.4658 (0.6164, 3.4861) /0.387	1.4134 (-1.7691, 4.5960) /0.384	1.4444 (0.6275, 3.3251) /0.387
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bronchitis					
Any Event	12 (4%)	10 (4%)	1.2089 (0.5137, 2.8449) /0.664	0.7067 (-2.4774, 3.8909) /0.664	1.2000 (0.5270, 2.7324) /0.664
Max Grade 1	8 (3%)	5 (2%)	1.6175 (0.5226, 5.0057) /0.404	1.0601 (-1.4066, 3.5268) /0.400	1.6000 (0.5299, 4.8314) /0.405
Max Grade 2	4 (1%)	5 (2%)	0.7971 (0.2118, 2.9997) /0.737	-0.3534 (-2.4143, 1.7076) /0.737	0.8000 (0.2171, 2.9484) /0.737
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Rhinitis					
Any Event	10 (4%)	10 (4%)	1.0000 (0.4097, 2.4411) />0.999	<0.0001 (-3.0420, 3.0420) />0.999	1.0000 (0.4228, 2.3653) />0.999
Max Grade 1	9 (3%)	9 (3%)	1.0000 (0.3910, 2.5574) />0.999	<0.0001 (-2.8912, 2.8912) />0.999	1.0000 (0.4029, 2.4822) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Syphilis					
Any Event	12 (4%)	6 (2%)	2.0443 (0.7564, 5.5247) /0.159	2.1201 (-0.7658, 5.0061) /0.150	2.0000 (0.7612, 5.2550) /0.160
Max Grade 1	8 (3%)	6 (2%)	1.3430 (0.4599, 3.9216) /0.590	0.7067 (-1.8517, 3.2651) /0.588	1.3333 (0.4686, 3.7935) /0.590
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oral herpes Any Event	11 (4%)	4 (1%)	2.8208 (0.8874, 8.9665) /0.079	2.4735 (-0.1652, 5.1122) /0.066	2.7500 (0.8862, 8.5339) /0.080
Max Grade 1	6 (2%)	4 (1%)	1.5108 (0.4217, 5.4123) /0.526	0.7067 (-1.4632, 2.8766) /0.523	1.5000 (0.4279, 5.2585) /0.526
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	2 (<1%)	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Folliculitis Any Event	8 (3%)	6 (2%)	1.3430 (0.4599, 3.9216) /0.590	0.7067 (-1.8517, 3.2651) /0.588	1.3333 (0.4686, 3.7935) /0.590
Max Grade 1	8 (3%)	5 (2%)	1.6175 (0.5226, 5.0057) /0.404	1.0601 (-1.4066, 3.5268) /0.400	1.6000 (0.5299, 4.8314) /0.405
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gonorrhoea					
Any Event	8 (3%)	6 (2%)	1.3430 (0.4599, 3.9216) /0.590	0.7067 (-1.8517, 3.2651) /0.588	1.3333 (0.4686, 3.7935) /0.590
Max Grade 1	5 (2%)	5 (2%)	1.0000 (0.2863, 3.4927) />0.999	<0.0001 (-2.1707, 2.1707) />0.999	1.0000 (0.2927, 3.4164) />0.999
Max Grade 2	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tonsillitis					
Any Event	8 (3%)	6 (2%)	1.3430 (0.4599, 3.9216) /0.590	0.7067 (-1.8517, 3.2651) /0.588	1.3333 (0.4686, 3.7935) /0.590
Max Grade 1	6 (2%)	5 (2%)	1.2043 (0.3633, 3.9922) /0.761	0.3534 (-1.9210, 2.6277) /0.761	1.2000 (0.3705, 3.8870) /0.761
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory tract infection Any Event	5 (2%)	8 (3%)	0.6183 (0.1998, 1.9134) /0.404	-1.0601 (-3.5268, 1.4066) /0.400	0.6250 (0.2070, 1.8873) /0.405
Max Grade 1	4 (1%)	7 (2%)	0.5653 (0.1636, 1.9528) /0.367	-1.0601 (-3.3329, 1.2128) /0.361	0.5714 (0.1691, 1.9305) /0.368
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Urinary tract infection					
Any Event	2 (<1%)	10 (4%)	0.1943 (0.0422, 0.8949) /0.036	-2.8269 (-5.1890, -0.4648) /0.019	0.2000 (0.0442, 0.9046) /0.037
Max Grade 1	1 (<1%)	7 (2%)	0.1398 (0.0171, 1.1439) /0.067	-2.1201 (-4.0573, -0.1830) /0.032	0.1429 (0.0177, 1.1536) /0.068
Max Grade 2	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Herpes simplex Any Event	6 (2%)	5 (2%)	1.2043 (0.3633, 3.9922) /0.761	0.3534 (-1.9210, 2.6277) /0.761	1.2000 (0.3705, 3.8870) /0.761
Max Grade 1	4 (1%)	5 (2%)	0.7971 (0.2118, 2.9997) /0.737	-0.3534 (-2.4143, 1.7076) /0.737	0.8000 (0.2171, 2.9484) /0.737
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Conjunctivitis					
Any Event	7 (2%)	3 (1%)	2.3671 (0.6059, 9.2476) /0.215	1.4134 (-0.7541, 3.5810) /0.201	2.3333 (0.6095, 8.9328) /0.216
Max Grade 1	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Furuncle					
Any Event	3 (1%)	7 (2%)	0.4224 (0.1081, 1.6504) /0.215	-1.4134 (-3.5810, 0.7541) /0.201	0.4286 (0.1119, 1.6407) /0.216
Max Grade 1	2 (<1%)	6 (2%)	0.3286 (0.0658, 1.6420) /0.175	-1.4134 (-3.3549, 0.5281) /0.154	0.3333 (0.0679, 1.6375) /0.176
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroenteritis viral					
Any Event	6 (2%)	4 (1%)	1.5108 (0.4217, 5.4123) /0.526	0.7067 (-1.4632, 2.8766) /0.523	1.5000 (0.4279, 5.2585) /0.526
Max Grade 1	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Herpes zoster					
Any Event	8 (3%)	1 (<1%)	8.2036 (1.0193, 66.0267) /0.048	2.4735 (0.4225, 4.5245) /0.018	8.0000 (1.0072, 63.5450) /0.049
Max Grade 1	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth infection Any Event	6 (2%)	3 (1%)	2.0217 (0.5006, 8.1641) /0.323	1.0601 (-0.9992, 3.1193) /0.313	2.0000 (0.5051, 7.9187) /0.324
Max Grade 1	6 (2%)	2 (<1%)	3.0433 (0.6090, 15.2082) /0.175	1.4134 (-0.5281, 3.3549) /0.154	3.0000 (0.6107, 14.7377) /0.176
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anal chlamydia infection					
Any Event	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Papilloma viral infection					
Any Event	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 1	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sinusitis					
Any Event	4 (1%)	4 (1%)	1.0000 (0.2476, 4.0382) />0.999	<0.0001 (-1.9450, 1.9450) />0.999	1.0000 (0.2526, 3.9593) />0.999
Max Grade 1	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 2	0	3 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Genital herpes Any Event	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hordeolum					
Any Event	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 1	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Laryngitis					
Any Event	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis gonococcal Any Event	3 (1%)	4 (1%)	0.7473 (0.1657, 3.3698) /0.705	-0.3534 (-2.1741, 1.4674) /0.704	0.7500 (0.1694, 3.3207) /0.705
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis					
Any Event	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis gonococcal Any Event	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cystitis					
Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear infection					
Any Event	2 (<1%)	4 (1%)	0.4964 (0.0902, 2.7323) /0.421	-0.7067 (-2.3931, 0.9797) /0.411	0.5000 (0.0923, 2.7080) /0.421
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pharyngotonsillitis					
Any Event	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cellulitis					
Any Event	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 1	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chlamydial infection					
Any Event	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 1	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genital herpes simplex					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lower respiratory tract infection					
Any Event	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 1	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal gonococcal infection					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Viral infection					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Body tinea					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fungal skin infection					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hepatitis A					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Infection					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Secondary syphilis					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subcutaneous abscess					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea versicolour					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth abscess					
Any Event	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Tracheobronchitis					
Any Event	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 1	0	3 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Ureaplasma infection					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epididymitis Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Helicobacter infection					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Proctitis chlamydial					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinea pedis					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral pharyngitis					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Viral upper respiratory tract infection					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvovaginal candidiasis					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acarodermatitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acute hepatitis B					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Acute hepatitis C					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anal abscess					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Balanitis candida					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Candida infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chronic tonsillitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Escherichia urinary tract infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Mycoplasma infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Onychomycosis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Orchitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Otitis externa					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Otitis media Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pneumonia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Staphylococcal skin infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinea infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tracheitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis chlamydial Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abscess Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abscess limb Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Acute sinusitis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Angular cheilitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anorectal human papilloma virus infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bacterial vulvovaginitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bronchitis pneumococcal Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Conjunctivitis bacterial					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dacryocystitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Erysipelas					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eyelid infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Fungal infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Gastroenteritis shigella					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Genital candidiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genital infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genitourinary chlamydia infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genitourinary tract gonococcal infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genitourinary tract infection Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gingivitis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Groin abscess					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Helicobacter gastritis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatitis E					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Herpes virus infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lice infestation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Mycoplasma genitalium infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Oophoritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oral infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Paronychia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pertussis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngeal chlamydia infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis streptococcal Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Post procedural infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Proctitis mycoplasmal Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pyelonephritis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory tract infection bacterial					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rotavirus infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sexually transmitted disease					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin candida					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Staphylococcal abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Strongyloidiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinea cruris					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Tonsillitis bacterial					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Upper respiratory tract infection bacterial					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis mycoplasmal Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vaginal infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Varicella					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Viral tonsillitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vulvovaginal mycotic infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvovaginitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

General disorders and administration site conditions					
Any Event	243 (86%)	26 (9%)	60.0489 (35.5590, 101.4052) /<.001	76.6784 (71.4059, 81.9509) /<.001	9.3462 (6.4600, 13.5218) /<.001
Max Grade 1	136 (48%)	21 (7%)	11.5426 (6.9872, 19.0679) /<.001	40.6360 (34.0627, 47.2094) /<.001	6.4762 (4.2171, 9.9454) /<.001
Max Grade 2	96 (34%)	4 (1%)	35.8073 (12.9482, 99.0226) /<.001	32.5088 (26.8240, 38.1937) /<.001	24.0000 (8.9489, 64.3656) /<.001
Max Grade 3	11 (4%)	1 (<1%)	11.4044 (1.4625, 88.9328) /0.020	3.5336 (1.1779, 5.8892) /0.003	10.9999 (1.4296, 84.6361) /0.021
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site pain					
Any Event	227 (80%)	0	>999 (>999, >999) /NC	78.7397 (66.1039, 91.3756) /<.001	NC
Max Grade 1	124 (44%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	92 (33%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	11 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site					
nodule					
Any Event	44 (16%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	39 (14%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site induration					
Any Event	38 (13%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	29 (10%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	8 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pyrexia					
Any Event	22 (8%)	4 (1%)	5.8793 (1.9993, 17.2890) /0.001	6.3604 (2.9511, 9.7697) /<.001	5.5000 (1.9198, 15.7570) /0.002
Max Grade 1	15 (5%)	2 (<1%)	7.8638 (1.7814, 34.7138) /0.006	4.5936 (1.8069, 7.3804) /0.001	7.5000 (1.7310, 32.4948) /0.007
Max Grade 2	6 (2%)	2 (<1%)	3.0433 (0.6090, 15.2082) /0.175	1.4134 (-0.5281, 3.3549) /0.154	3.0000 (0.6107, 14.7377) /0.176
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site swelling					
Any Event	23 (8%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	19 (7%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			
Injection site pruritus					
Any Event	16 (6%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	16 (6%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fatigue					
Any Event	7 (2%)	8 (3%)	0.8718 (0.3119, 2.4373) /0.794	-0.3534 (-2.9997, 2.2930) /0.794	0.8750 (0.3216, 2.3807) /0.794
Max Grade 1	5 (2%)	7 (2%)	0.7091 (0.2224, 2.2614) /0.561	-0.7067 (-3.0796, 1.6661) /0.559	0.7143 (0.2294, 2.2239) /0.561
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza like illness					
Any Event	8 (3%)	7 (2%)	1.1470 (0.4103, 3.2065) /0.794	0.3534 (-2.2930, 2.9997) /0.794	1.1429 (0.4201, 3.1094) /0.794
Max Grade 1	7 (2%)	7 (2%)	1.0000 (0.3462, 2.8888) />0.999	<0.0001 (-2.5591, 2.5591) />0.999	1.0000 (0.3554, 2.8140) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Asthenia					
Any Event	12 (4%)	1 (<1%)	12.4871 (1.6127, 96.6882) /0.016	3.8869 (1.4395, 6.3343) /0.002	11.9999 (1.5708, 91.6730) /0.017
Max Grade 1	10 (4%)	1 (<1%)	10.3297 (1.3135, 81.2372) /0.026	3.1802 (0.9208, 5.4396) /0.006	10.0000 (1.2886, 77.6017) /0.028
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site erythema					
Any Event	13 (5%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	10 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site warmth					
Any Event	8 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Malaise					
Any Event	7 (2%)	1 (<1%)	7.1522 (0.8742, 58.5141) /0.067	2.1201 (0.1830, 4.0573) /0.032	7.0000 (0.8668, 56.5261) /0.068
Max Grade 1	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site bruising					
Any Event	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Discomfort Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site haematoma					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nodule					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Chest pain					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Feeling hot					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site discolouration					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site haemorrhage					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Catheter site erythema					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Chest discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Chills					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site anaesthesia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site cyst					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site granuloma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site necrosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site scar					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Non-cardiac chest pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oedema peripheral					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Swelling					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Systemic inflammatory response syndrome					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Temperature regulation disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vessel puncture site bruise					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	107 (38%)	75 (27%)	1.6861 (1.1799, 2.4093) /0.004	11.3074 (3.6682, 18.9467) /0.004	1.4267 (1.1168, 1.8225) /0.004
Max Grade 1	72 (25%)	62 (22%)	1.2163 (0.8248, 1.7937) /0.323	3.5336 (-3.4644, 10.5315) /0.322	1.1613 (0.8630, 1.5628) /0.324
Max Grade 2	34 (12%)	12 (4%)	3.0837 (1.5619, 6.0882) /0.001	7.7739 (3.3173, 12.2304) /<.001	2.8333 (1.4983, 5.3581) /0.001
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diarrhoea					
Any Event	32 (11%)	25 (9%)	1.3157 (0.7581, 2.2833) /0.329	2.4735 (-2.4808, 7.4278) /0.328	1.2800 (0.7790, 2.1031) /0.330
Max Grade 1	20 (7%)	21 (7%)	0.9488 (0.5024, 1.7918) /0.871	-0.3534 (-4.6242, 3.9175) /0.871	0.9524 (0.5280, 1.7177) /0.871
Max Grade 2	12 (4%)	4 (1%)	3.0885 (0.9840, 9.6946) /0.053	2.8269 (0.1060, 5.5477) /0.042	3.0000 (0.9793, 9.1902) /0.054
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nausea					
Any Event	16 (6%)	11 (4%)	1.4818 (0.6752, 3.2520) /0.327	1.7668 (-1.7420, 5.2756) /0.324	1.4545 (0.6872, 3.0786) /0.327
Max Grade 1	15 (5%)	9 (3%)	1.7040 (0.7331, 3.9604) /0.215	2.1201 (-1.1954, 5.4357) /0.210	1.6667 (0.7416, 3.7458) /0.216
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal pain					
Any Event	12 (4%)	8 (3%)	1.5221 (0.6126, 3.7822) /0.366	1.4134 (-1.6264, 4.4532) /0.362	1.5000 (0.6226, 3.6138) /0.366
Max Grade 1	8 (3%)	7 (2%)	1.1470 (0.4103, 3.2065) /0.794	0.3534 (-2.2930, 2.9997) /0.794	1.1429 (0.4201, 3.1094) /0.794
Max Grade 2	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoids					
Any Event	16 (6%)	3 (1%)	5.5930 (1.6113, 19.4137) /0.007	4.5936 (1.6501, 7.5371) /0.002	5.3333 (1.5713, 18.1022) /0.007
Max Grade 1	13 (5%)	2 (<1%)	6.7648 (1.5124, 30.2584) /0.012	3.8869 (1.2599, 6.5140) /0.004	6.5000 (1.4803, 28.5414) /0.013
Max Grade 2	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Toothache					
Any Event	7 (2%)	5 (2%)	1.4101 (0.4422, 4.4967) /0.561	0.7067 (-1.6661, 3.0796) /0.559	1.4000 (0.4497, 4.3589) /0.561
Max Grade 1	6 (2%)	3 (1%)	2.0217 (0.5006, 8.1641) /0.323	1.0601 (-0.9992, 3.1193) /0.313	2.0000 (0.5051, 7.9187) /0.324
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vomiting					
Any Event	8 (3%)	3 (1%)	2.7152 (0.7129, 10.3413) /0.143	1.7668 (-0.5031, 4.0367) /0.127	2.6667 (0.7148, 9.9489) /0.144
Max Grade 1	6 (2%)	1 (<1%)	6.1083 (0.7306, 51.0668) /0.095	1.7668 (-0.0484, 3.5820) /0.056	6.0000 (0.7270, 49.5178) /0.096
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Constipation					
Any Event	7 (2%)	3 (1%)	2.3671 (0.6059, 9.2476) /0.215	1.4134 (-0.7541, 3.5810) /0.201	2.3333 (0.6095, 8.9328) /0.216
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dyspepsia					
Any Event	7 (2%)	3 (1%)	2.3671 (0.6059, 9.2476) /0.215	1.4134 (-0.7541, 3.5810) /0.201	2.3333 (0.6095, 8.9328) /0.216
Max Grade 1	6 (2%)	3 (1%)	2.0217 (0.5006, 8.1641) /0.323	1.0601 (-0.9992, 3.1193) /0.313	2.0000 (0.5051, 7.9187) /0.324
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis					
Any Event	7 (2%)	2 (<1%)	3.5634 (0.7338, 17.3040) /0.115	1.7668 (-0.2892, 3.8228) /0.092	3.5000 (0.7334, 16.7027) /0.116
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal pain upper					
Any Event	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastritis					
Any Event	4 (1%)	3 (1%)	1.3381 (0.2968, 6.0337) /0.705	0.3534 (-1.4674, 2.1741) /0.704	1.3333 (0.3011, 5.9034) /0.705
Max Grade 1	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anogenital dysplasia					
Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dental caries					
Any Event	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Food poisoning Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Odynophagia					
Any Event	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Flatulence					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroesophageal reflux disease					
Any Event	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 1	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Proctalgia					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal pain lower					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal fissure					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoidal haemorrhage Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal discomfort					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal distension					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anal inflammation					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Diarrhoea haemorrhagic					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dry mouth					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Faeces soft					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Gastroduodenitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gingival bleeding					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

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

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Inguinal hernia					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lip dry					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rectal haemorrhage					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Stomatitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Aerophagia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anal fistula					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal pruritus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anal ulcer					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Aphthous ulcer					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Barrett's oesophagus Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bile acid malabsorption					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Bowel movement irregularity					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Colitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Colitis microscopic Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dysbacteriosis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Enteritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Enterocolitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epigastric discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal sounds abnormal					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gingival pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gingival swelling					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Haematochezia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Irritable bowel syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Large intestine perforation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			
Leukoplakia oral					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lymphoid hyperplasia of intestine					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oesophageal polyp					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oral pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Palatal ulcer Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Pancreatitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Paraesthesia oral					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rectal discharge					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rectal fissure Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			
Tongue eruption Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Tooth development disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Umbilical hernia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal and connective tissue disorders					
Any Event	64 (23%)	44 (16%)	1.5874 (1.0374, 2.4289) /0.033	7.0671 (0.6190, 13.5153) /0.032	1.4545 (1.0284, 2.0572) /0.034
Max Grade 1	46 (16%)	34 (12%)	1.4214 (0.8817, 2.2917) /0.149	4.2403 (-1.4891, 9.9697) /0.147	1.3529 (0.8965, 2.0417) /0.150
Max Grade 2	16 (6%)	10 (4%)	1.6360 (0.7293, 3.6697) /0.232	2.1201 (-1.3248, 5.5651) /0.228	1.6000 (0.7388, 3.4650) /0.233
Max Grade 3	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Back pain					
Any Event	22 (8%)	13 (5%)	1.7507 (0.8638, 3.5482) /0.120	3.1802 (-0.7797, 7.1401) /0.115	1.6923 (0.8698, 3.2925) /0.121
Max Grade 1	15 (5%)	9 (3%)	1.7040 (0.7331, 3.9604) /0.215	2.1201 (-1.1954, 5.4357) /0.210	1.6667 (0.7416, 3.7458) /0.216
Max Grade 2	7 (2%)	4 (1%)	1.7690 (0.5121, 6.1111) /0.367	1.0601 (-1.2128, 3.3329) /0.361	1.7500 (0.5180, 5.9120) /0.368
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Myalgia					
Any Event	14 (5%)	5 (2%)	2.8937 (1.0281, 8.1443) /0.044	3.1802 (0.2241, 6.1364) /0.035	2.8000 (1.0221, 7.6703) /0.045
Max Grade 1	12 (4%)	4 (1%)	3.0885 (0.9840, 9.6946) /0.053	2.8269 (0.1060, 5.5477) /0.042	3.0000 (0.9793, 9.1902) /0.054
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthralgia					
Any Event	9 (3%)	7 (2%)	1.2951 (0.4756, 3.5267) /0.613	0.7067 (-2.0235, 3.4369) /0.612	1.2857 (0.4855, 3.4049) /0.613
Max Grade 1	6 (2%)	6 (2%)	1.0000 (0.3186, 3.1386) />0.999	<0.0001 (-2.3736, 2.3736) />0.999	1.0000 (0.3264, 3.0634) />0.999
Max Grade 2	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle contracture					
Any Event	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle spasms					
Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Musculoskeletal chest pain Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal pain					
Any Event	1 (<1%)	5 (2%)	0.1972 (0.0229, 1.6984) /0.139	-1.4134 (-3.0968, 0.2700) /0.100	0.2000 (0.0235, 1.7011) /0.141
Max Grade 1	1 (<1%)	5 (2%)	0.1972 (0.0229, 1.6984) /0.139	-1.4134 (-3.0968, 0.2700) /0.100	0.2000 (0.0235, 1.7011) /0.141
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain in extremity					
Any Event	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neck pain					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Osteochondrosis					
Any Event	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tendonitis					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal discomfort					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Musculoskeletal stiffness					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Osteoarthritis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Plantar fasciitis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Spinal disorder					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Spinal osteoarthritis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bursitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Groin pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Intervertebral disc disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Joint swelling					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Osteonecrosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Osteoporosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rotator cuff syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Soft tissue mass					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Temporomandibular joint syndrome					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tendon pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vertebral foraminal stenosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nervous system disorders					
Any Event	64 (23%)	33 (12%)	2.2139 (1.4011, 3.4984) /<.001	10.9541 (4.8109, 17.0972) /<.001	1.9394 (1.3179, 2.8541) /<.001
Max Grade 1	47 (17%)	24 (8%)	2.1492 (1.2747, 3.6237) /0.004	8.1272 (2.7110, 13.5434) /0.003	1.9583 (1.2322, 3.1124) /0.004
Max Grade 2	16 (6%)	9 (3%)	1.8244 (0.7925, 4.2001) /0.158	2.4735 (-0.9059, 5.8529) /0.151	1.7778 (0.7989, 3.9559) /0.159
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Headache					
Any Event	39 (14%)	21 (7%)	1.9941 (1.1409, 3.4856) /0.015	6.3604 (1.3153, 11.4056) /0.013	1.8571 (1.1216, 3.0750) /0.016
Max Grade 1	28 (10%)	17 (6%)	1.7181 (0.9181, 3.2151) /0.090	3.8869 (-0.5589, 8.3328) /0.087	1.6471 (0.9225, 2.9407) /0.092
Max Grade 2	11 (4%)	4 (1%)	2.8208 (0.8874, 8.9665) /0.079	2.4735 (-0.1652, 5.1122) /0.066	2.7500 (0.8862, 8.5339) /0.080
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dizziness					
Any Event	15 (5%)	3 (1%)	5.2239 (1.4954, 18.2487) /0.010	4.2403 (1.3703, 7.1103) /0.004	5.0000 (1.4635, 17.0821) /0.010
Max Grade 1	13 (5%)	3 (1%)	4.4938 (1.2665, 15.9454) /0.020	3.5336 (0.8183, 6.2488) /0.011	4.3333 (1.2483, 15.0422) /0.021
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sciatica					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Migraine					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Paraesthesia					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Syncope					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Amnesia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Disturbance in attention					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Dysarthria					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lethargy					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neuropathy peripheral Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Poor quality sleep					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Presyncope					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Somnolence					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anosmia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Autonomic nervous system imbalance					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cervical neuritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypoaesthesia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Intercostal neuralgia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nerve compression					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Post herpetic neuralgia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Radiculitis brachial					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tension headache					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tremor					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Trigeminal neuralgia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Visual field defect					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin and subcutaneous tissue disorders					
Any Event	47 (17%)	32 (11%)	1.5621 (0.9636, 2.5322) /0.070	5.3004 (-0.3929, 10.9936) /0.068	1.4687 (0.9671, 2.2307) /0.071
Max Grade 1	39 (14%)	25 (9%)	1.6495 (0.9692, 2.8074) /0.065	4.9470 (-0.2550, 10.1490) /0.062	1.5600 (0.9708, 2.5069) /0.066
Max Grade 2	7 (2%)	7 (2%)	1.0000 (0.3462, 2.8888) />0.999	<0.0001 (-2.5591, 2.5591) />0.999	1.0000 (0.3554, 2.8140) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash					
Any Event	6 (2%)	8 (3%)	0.7446 (0.2550, 2.1742) /0.590	-0.7067 (-3.2651, 1.8517) /0.588	0.7500 (0.2636, 2.1338) /0.590
Max Grade 1	5 (2%)	5 (2%)	1.0000 (0.2863, 3.4927) />0.999	<0.0001 (-2.1707, 2.1707) />0.999	1.0000 (0.2927, 3.4164) />0.999
Max Grade 2	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eczema					
Any Event	7 (2%)	6 (2%)	1.1709 (0.3886, 3.5284) /0.779	0.3534 (-2.1147, 2.8214) /0.779	1.1667 (0.3970, 3.4283) /0.779
Max Grade 1	7 (2%)	5 (2%)	1.4101 (0.4422, 4.4967) /0.561	0.7067 (-1.6661, 3.0796) /0.559	1.4000 (0.4497, 4.3589) /0.561
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acne					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Seborrhoeic dermatitis					
Any Event	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 1	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dermatitis					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Erythema					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hyperhidrosis Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin lesion					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dermal cyst					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dermatitis atopic					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dyshidrotic eczema					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Intertrigo					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Night sweats					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Papule					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pityriasis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pruritus generalised					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Rash pruritic					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash vesicular Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin mass					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Urticaria					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Alopecia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Blood blister					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dandruff					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dermatitis allergic					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ephelides					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Granuloma annulare					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Lipodystrophy acquired					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nail pigmentation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Penile ulceration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pityriasis alba					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pruritus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Psoriasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Purpura					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rash generalised					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash macular					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Rash maculo-papular					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Rash morbilliform Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rash papular Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Rosacea					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin erosion					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin hyperpigmentation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin hypopigmentation Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin induration Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin reaction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Xeroderma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory, thoracic and mediastinal disorders					
Any Event	43 (15%)	34 (12%)	1.3121 (0.8091, 2.1279) /0.271	3.1802 (-2.4625, 8.8229) /0.269	1.2647 (0.8322, 1.9220) /0.271
Max Grade 1	29 (10%)	27 (10%)	1.0825 (0.6232, 1.8803) /0.778	0.7067 (-4.2126, 5.6260) /0.778	1.0741 (0.6530, 1.7666) /0.778
Max Grade 2	13 (5%)	7 (2%)	1.8984 (0.7460, 4.8310) /0.179	2.1201 (-0.9169, 5.1572) /0.171	1.8571 (0.7521, 4.5859) /0.180
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cough					
Any Event	10 (4%)	12 (4%)	0.8272 (0.3515, 1.9468) /0.664	-0.7067 (-3.8909, 2.4774) /0.664	0.8333 (0.3660, 1.8975) /0.664
Max Grade 1	5 (2%)	9 (3%)	0.5476 (0.1812, 1.6547) /0.286	-1.4134 (-3.9699, 1.1430) /0.279	0.5556 (0.1885, 1.6371) /0.286
Max Grade 2	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal pain					
Any Event	12 (4%)	4 (1%)	3.0885 (0.9840, 9.6946) /0.053	2.8269 (0.1060, 5.5477) /0.042	3.0000 (0.9793, 9.1902) /0.054
Max Grade 1	8 (3%)	4 (1%)	2.0291 (0.6040, 6.8162) /0.252	1.4134 (-0.9573, 3.7841) /0.243	2.0000 (0.6091, 6.5667) /0.253
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinitis allergic					
Any Event	10 (4%)	1 (<1%)	10.3297 (1.3135, 81.2372) /0.026	3.1802 (0.9208, 5.4396) /0.006	10.0000 (1.2886, 77.6017) /0.028
Max Grade 1	7 (2%)	1 (<1%)	7.1522 (0.8742, 58.5141) /0.067	2.1201 (0.1830, 4.0573) /0.032	7.0000 (0.8668, 56.5261) /0.068
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Catarrh					
Any Event	5 (2%)	4 (1%)	1.2545 (0.3334, 4.7207) /0.737	0.3534 (-1.7076, 2.4143) /0.737	1.2500 (0.3392, 4.6069) /0.737
Max Grade 1	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal congestion					
Any Event	2 (<1%)	5 (2%)	0.3957 (0.0761, 2.0568) /0.270	-1.0601 (-2.8790, 0.7588) /0.253	0.4000 (0.0783, 2.0447) /0.271
Max Grade 1	1 (<1%)	4 (1%)	0.2473 (0.0275, 2.2268) /0.213	-1.0601 (-2.5994, 0.4792) /0.177	0.2500 (0.0281, 2.2229) /0.214
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinorrhoea					
Any Event	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Asthma					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epistaxis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Productive cough					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory disorder					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Sinus congestion					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bronchial obstruction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Bronchitis chronic					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bronchospasm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Nasal dryness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nasal obstruction					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nasal turbinate hypertrophy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nasal ulcer					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Reflux laryngitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Throat irritation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tonsillar hypertrophy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Upper respiratory tract inflammation Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Wheezing					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injury, poisoning and procedural complications					
Any Event	31 (11%)	37 (13%)	0.8179 (0.4919, 1.3600) /0.438	-2.1201 (-7.4743, 3.2340) /0.438	0.8378 (0.5354, 1.3112) /0.439
Max Grade 1	18 (6%)	23 (8%)	0.7678 (0.4048, 1.4563) /0.419	-1.7668 (-6.0353, 2.5017) /0.417	0.7826 (0.4319, 1.4180) /0.419
Max Grade 2	11 (4%)	12 (4%)	0.9133 (0.3962, 2.1055) /0.831	-0.3534 (-3.6065, 2.8998) /0.831	0.9167 (0.4113, 2.0429) /0.831
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthropod bite					
Any Event	3 (1%)	7 (2%)	0.4224 (0.1081, 1.6504) /0.215	-1.4134 (-3.5810, 0.7541) /0.201	0.4286 (0.1119, 1.6407) /0.216
Max Grade 1	1 (<1%)	7 (2%)	0.1398 (0.0171, 1.1439) /0.067	-2.1201 (-4.0573, -0.1830) /0.032	0.1429 (0.0177, 1.1536) /0.068
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Contusion					
Any Event	7 (2%)	2 (<1%)	3.5634 (0.7338, 17.3040) /0.115	1.7668 (-0.2892, 3.8228) /0.092	3.5000 (0.7334, 16.7027) /0.116
Max Grade 1	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Laceration					
Any Event	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthropod sting					
Any Event	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Thermal burn					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ankle fracture					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fall					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ligament sprain Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Limb injury Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Meniscus injury					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Multiple injuries					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle strain Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Penis injury Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Procedural pain Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin abrasion Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Wound					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bone contusion					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Craniocerebral injury					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Epicondylitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Exposure via inhalation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Foot fracture					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hand fracture Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Heat stroke Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Joint dislocation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Joint injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Neck injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Penile contusion					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Post lumbar puncture syndrome					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Post procedural haemorrhage					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rib fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Road traffic accident					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			
Skin injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Soft tissue injury					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Spinal column injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Sunburn					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Tendon injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tibia fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Traumatic haematoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Urethral injury					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Investigations					
Any Event	41 (14%)	27 (10%)	1.6064 (0.9583, 2.6927) /0.072	4.9470 (-0.3945, 10.2885) /0.069	1.5185 (0.9615, 2.3982) /0.073
Max Grade 1	20 (7%)	11 (4%)	1.8804 (0.8838, 4.0008) /0.101	3.1802 (-0.5596, 6.9200) /0.096	1.8182 (0.8876, 3.7243) /0.102
Max Grade 2	11 (4%)	12 (4%)	0.9133 (0.3962, 2.1055) /0.831	-0.3534 (-3.6065, 2.8998) /0.831	0.9167 (0.4113, 2.0429) /0.831
Max Grade 3	5 (2%)	4 (1%)	1.2545 (0.3334, 4.7207) /0.737	0.3534 (-1.7076, 2.4143) /0.737	1.2500 (0.3392, 4.6069) /0.737
Max Grade 4	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatine phosphokinase increased					
Any Event	9 (3%)	6 (2%)	1.5164 (0.5326, 4.3179) /0.435	1.0601 (-1.5850, 3.7051) /0.432	1.5000 (0.5410, 4.1588) /0.436
Max Grade 1	2 (<1%)	4 (1%)	0.4964 (0.0902, 2.7323) /0.421	-0.7067 (-2.3931, 0.9797) /0.411	0.5000 (0.0923, 2.7080) /0.421
Max Grade 2	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Body temperature increased					
Any Event	9 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	9 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lipase increased					
Any Event	4 (1%)	4 (1%)	1.0000 (0.2476, 4.0382) />0.999	<0.0001 (-1.9450, 1.9450) />0.999	1.0000 (0.2526, 3.9593) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Creatinine renal clearance decreased					
Any Event	3 (1%)	4 (1%)	0.7473 (0.1657, 3.3698) /0.705	-0.3534 (-2.1741, 1.4674) /0.704	0.7500 (0.1694, 3.3207) /0.705
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Aspartate aminotransferase increased					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Alanine aminotransferase increased					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Glomerular filtration rate decreased					
Any Event	0	3 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	3 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D decreased					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Weight decreased					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			
Blood glucose abnormal					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Transaminases increased					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Aortic bruit					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood cholesterol increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatinine increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood folate decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood triglycerides increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Carbon dioxide decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Electrocardiogram QT prolonged Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Electrocardiogram repolarisation abnormality					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemoglobin decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Heart rate increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatic enzyme increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Low density lipoprotein increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Mycoplasma test positive					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nuclear magnetic resonance imaging brain abnormal					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Platelet count decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Protein urine present					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Total lung capacity decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Treponema test positive					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Weight increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
White blood cell count decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Psychiatric disorders					
Any Event	38 (13%)	27 (10%)	1.4706 (0.8712, 2.4823) /0.149	3.8869 (-1.3566, 9.1304) /0.146	1.4074 (0.8840, 2.2406) /0.150
Max Grade 1	26 (9%)	17 (6%)	1.5830 (0.8390, 2.9868) /0.156	3.1802 (-1.1775, 7.5379) /0.153	1.5294 (0.8489, 2.7555) /0.157
Max Grade 2	11 (4%)	9 (3%)	1.2312 (0.5022, 3.0185) /0.649	0.7067 (-2.3348, 3.7482) /0.649	1.2222 (0.5144, 2.9039) /0.649
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anxiety					
Any Event	13 (5%)	6 (2%)	2.2228 (0.8328, 5.9330) /0.111	2.4735 (-0.4872, 5.4342) /0.102	2.1667 (0.8353, 5.6203) /0.112
Max Grade 1	9 (3%)	3 (1%)	3.0657 (0.8212, 11.4443) /0.096	2.1201 (-0.2470, 4.4873) /0.079	3.0000 (0.8207, 10.9663) /0.097
Max Grade 2	3 (1%)	3 (1%)	1.0000 (0.2001, 4.9971) />0.999	<0.0001 (-1.6874, 1.6874) />0.999	1.0000 (0.2036, 4.9126) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Insomnia					
Any Event	7 (2%)	4 (1%)	1.7690 (0.5121, 6.1111) /0.367	1.0601 (-1.2128, 3.3329) /0.361	1.7500 (0.5180, 5.9120) /0.368
Max Grade 1	6 (2%)	2 (<1%)	3.0433 (0.6090, 15.2082) /0.175	1.4134 (-0.5281, 3.3549) /0.154	3.0000 (0.6107, 14.7377) /0.176
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depression					
Any Event	6 (2%)	4 (1%)	1.5108 (0.4217, 5.4123) /0.526	0.7067 (-1.4632, 2.8766) /0.523	1.5000 (0.4279, 5.2585) /0.526
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abnormal dreams					
Any Event	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 1	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Sleep disorder					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depressed mood					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Libido decreased					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Adjustment disorder					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Panic attack					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Adjustment disorder with depressed mood					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nervousness					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nightmare					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Stress					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Suicidal ideation					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute stress disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Affect lability					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Affective disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anxiety disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Drug abuse					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Intentional self-injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Major depression					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Paranoia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Suicide attempt					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Metabolism and nutrition disorders					
Any Event	33 (12%)	23 (8%)	1.4922 (0.8524, 2.6122) /0.161	3.5336 (-1.3774, 8.4446) /0.158	1.4348 (0.8648, 2.3804) /0.162
Max Grade 1	26 (9%)	15 (5%)	1.8075 (0.9360, 3.4906) /0.078	3.8869 (-0.3720, 8.1459) /0.074	1.7333 (0.9383, 3.2021) /0.079
Max Grade 2	5 (2%)	7 (2%)	0.7091 (0.2224, 2.2614) /0.561	-0.7067 (-3.0796, 1.6661) /0.559	0.7143 (0.2294, 2.2239) /0.561
Max Grade 3	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D deficiency					
Any Event	23 (8%)	13 (5%)	1.8373 (0.9114, 3.7038) /0.089	3.5336 (-0.4770, 7.5441) /0.084	1.7692 (0.9146, 3.4225) /0.090
Max Grade 1	21 (7%)	10 (4%)	2.1882 (1.0112, 4.7348) /0.047	3.8869 (0.1517, 7.6222) /0.041	2.1000 (1.0072, 4.3786) /0.048
Max Grade 2	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypophosphataemi ^a					
Any Event	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypovitaminosis Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypercholesterolemia					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Type 2 diabetes mellitus					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hyperlipasaemia Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypertriglyceridemia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diabetes mellitus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diabetic ketoacidosis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Glucose tolerance impaired					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gout					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypocalcaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hypokalaemia Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypomagnesaemia Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Increased appetite					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Iron deficiency					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lactose intolerance					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	23 (8%)	19 (7%)	1.2291 (0.6538, 2.3108) /0.522	1.4134 (-2.9036, 5.7305) /0.521	1.2105 (0.6745, 2.1726) /0.522
Max Grade 1	17 (6%)	15 (5%)	1.1419 (0.5587, 2.3335) /0.716	0.7067 (-3.0982, 4.5117) /0.716	1.1333 (0.5773, 2.2247) /0.716
Max Grade 2	4 (1%)	4 (1%)	1.0000 (0.2476, 4.0382) />0.999	<0.0001 (-1.9450, 1.9450) />0.999	1.0000 (0.2526, 3.9593) />0.999
Max Grade 3	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anogenital warts					
Any Event	12 (4%)	6 (2%)	2.0443 (0.7564, 5.5247) /0.159	2.1201 (-0.7658, 5.0061) /0.150	2.0000 (0.7612, 5.2550) /0.160
Max Grade 1	11 (4%)	4 (1%)	2.8208 (0.8874, 8.9665) /0.079	2.4735 (-0.1652, 5.1122) /0.066	2.7500 (0.8862, 8.5339) /0.080
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin papilloma					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 1	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Acrochordon					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Lipoma					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Melanocytic naevus					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oral papilloma					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Uterine leiomyoma					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Adenocarcinoma of colon					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal neoplasm					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Benign spleen tumour					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Breast cancer					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dysplastic naevus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Kaposi's sarcoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Kidney angiomyolipoma Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Neoplasm skin Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oral fibroma Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin cancer Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Reproductive system and breast disorders					
Any Event	19 (7%)	18 (6%)	1.0596 (0.5439, 2.0640) /0.865	0.3534 (-3.7192, 4.4260) /0.865	1.0556 (0.5660, 1.9686) /0.865
Max Grade 1	13 (5%)	13 (5%)	1.0000 (0.4552, 2.1969) />0.999	<0.0001 (-3.4493, 3.4493) />0.999	1.0000 (0.4719, 2.1189) />0.999
Max Grade 2	6 (2%)	5 (2%)	1.2043 (0.3633, 3.9922) /0.761	0.3534 (-1.9210, 2.6277) /0.761	1.2000 (0.3705, 3.8870) /0.761
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cervical dysplasia Any Event	6 (2%)	2 (<1%)	3.0433 (0.6090, 15.2082) /0.175	1.4134 (-0.5281, 3.3549) /0.154	3.0000 (0.6107, 14.7377) /0.176
Max Grade 1	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Erectile dysfunction Any Event	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Breast mass Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Prostatitis Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Atrophic vulvovaginitis Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Genital lesion Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Breast discharge					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Breast pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cervix disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Dysfunctional uterine bleeding					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Dysmenorrhoea					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Menopausal symptoms					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Menstruation irregular					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ovarian cyst					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Penile pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Polymenorrhoea					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Priapism					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Testicular pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal discharge					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal dysplasia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal haemorrhage Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vaginal ulceration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Varicocele					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvar dysplasia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Vulvovaginal pruritus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Blood and lymphatic system disorders					
Any Event	15 (5%)	11 (4%)	1.3840 (0.6243, 3.0681) /0.424	1.4134 (-2.0340, 4.8608) /0.422	1.3636 (0.6375, 2.9169) /0.424
Max Grade 1	12 (4%)	7 (2%)	1.7459 (0.6772, 4.5013) /0.249	1.7668 (-1.1974, 4.7309) /0.243	1.7143 (0.6849, 4.2908) /0.250
Max Grade 2	2 (<1%)	4 (1%)	0.4964 (0.0902, 2.7323) /0.421	-0.7067 (-2.3931, 0.9797) /0.411	0.5000 (0.0923, 2.7080) /0.421
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anaemia					
Any Event	6 (2%)	4 (1%)	1.5108 (0.4217, 5.4123) /0.526	0.7067 (-1.4632, 2.8766) /0.523	1.5000 (0.4279, 5.2585) /0.526
Max Grade 1	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lymphadenopathy Any Event	2 (<1%)	4 (1%)	0.4964 (0.0902, 2.7323) /0.421	-0.7067 (-2.3931, 0.9797) /0.411	0.5000 (0.0923, 2.7080) /0.421
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eosinophilia					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Iron deficiency anaemia					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypochromic anaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Leukocytosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lymphadenitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Max Grade NA	1 (<1%)	0			
Normocytic anaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Splenomegaly					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal and urinary disorders					
Any Event	13 (5%)	9 (3%)	1.4658 (0.6164, 3.4861) /0.387	1.4134 (-1.7691, 4.5960) /0.384	1.4444 (0.6275, 3.3251) /0.387
Max Grade 1	11 (4%)	7 (2%)	1.5945 (0.6091, 4.1741) /0.342	1.4134 (-1.4754, 4.3023) /0.338	1.5714 (0.6180, 3.9956) /0.342
Max Grade 2	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dysuria					
Any Event	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 1	5 (2%)	2 (<1%)	2.5270 (0.4862, 13.1340) /0.270	1.0601 (-0.7588, 2.8790) /0.253	2.5000 (0.4891, 12.7792) /0.271
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proteinuria					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haematuria					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Renal failure					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Calculus urinary					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Glomerulonephritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Micturition urgency					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nephrolithiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Nephropathy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pollakiuria					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethral caruncle					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Urethral discharge					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Urethral pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urinary incontinence					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eye disorders					
Any Event	12 (4%)	8 (3%)	1.5221 (0.6126, 3.7822) /0.366	1.4134 (-1.6264, 4.4532) /0.362	1.5000 (0.6226, 3.6138) /0.366
Max Grade 1	8 (3%)	7 (2%)	1.1470 (0.4103, 3.2065) /0.794	0.3534 (-2.2930, 2.9997) /0.794	1.1429 (0.4201, 3.1094) /0.794
Max Grade 2	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Blepharitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Asthenopia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Astigmatism					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Blepharospasm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Cataract					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Chalazion					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chorioretinal disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Conjunctivitis allergic					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Diabetic retinopathy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dry eye					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eye allergy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eye irritation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eye pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eye pruritus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Glare					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Glaucoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lacrimation increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Meibomian gland dysfunction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Myopia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Uveitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Vitreous detachment					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Ear and labyrinth disorders					
Any Event	10 (4%)	6 (2%)	1.6911 (0.6063, 4.7171) /0.315	1.4134 (-1.3149, 4.1418) /0.310	1.6667 (0.6140, 4.5242) /0.316
Max Grade 1	7 (2%)	6 (2%)	1.1709 (0.3886, 3.5284) /0.779	0.3534 (-2.1147, 2.8214) /0.779	1.1667 (0.3970, 3.4283) /0.779
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vertigo					
Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear pain					
Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Max Grade 1	1 (<1%)	3 (1%)	0.3310 (0.0342, 3.2010) /0.340	-0.7067 (-2.0857, 0.6723) /0.315	0.3333 (0.0349, 3.1853) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Max Grade NA	1 (<1%)	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cerumen impaction					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypoacusis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vertigo positional					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Deafness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Noninfective myringitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinnitus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vascular disorders					
Any Event	10 (4%)	4 (1%)	2.5549 (0.7918, 8.2441) /0.117	2.1201 (-0.4330, 4.6733) /0.104	2.5000 (0.7934, 7.8778) /0.118
Max Grade 1	5 (2%)	3 (1%)	1.6787 (0.3973, 7.0918) /0.481	0.7067 (-1.2374, 2.6508) /0.476	1.6667 (0.4021, 6.9079) /0.481
Max Grade 2	5 (2%)	1 (<1%)	5.0719 (0.5888, 43.6908) /0.139	1.4134 (-0.2700, 3.0968) /0.100	5.0000 (0.5879, 42.5266) /0.141
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypertension Any Event	4 (1%)	2 (<1%)	2.0143 (0.3660, 11.0865) /0.421	0.7067 (-0.9797, 2.3931) /0.411	2.0000 (0.3693, 10.8321) /0.421
Max Grade 1	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Circulatory collapse					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hot flush					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hyperaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypertensive crisis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Intermittent claudication					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral artery thrombosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral ischaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral venous disease					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Thrombophlebitis superficial					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Immune system disorders					
Any Event	10 (4%)	3 (1%)	3.4188 (0.9309, 12.5563) /0.064	2.4735 (0.0137, 4.9333) /0.049	3.3333 (0.9271, 11.9845) /0.065
Max Grade 1	10 (4%)	3 (1%)	3.4188 (0.9309, 12.5563) /0.064	2.4735 (0.0137, 4.9333) /0.049	3.3333 (0.9271, 11.9845) /0.065
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Seasonal allergy					
Any Event	6 (2%)	1 (<1%)	6.1083 (0.7306, 51.0668) /0.095	1.7668 (-0.0484, 3.5820) /0.056	6.0000 (0.7270, 49.5178) /0.096
Max Grade 1	6 (2%)	1 (<1%)	6.1083 (0.7306, 51.0668) /0.095	1.7668 (-0.0484, 3.5820) /0.056	6.0000 (0.7270, 49.5178) /0.096
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypersensitivity					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Food allergy					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mite allergy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatobiliary disorders					
Any Event	6 (2%)	1 (<1%)	6.1083 (0.7306, 51.0668) /0.095	1.7668 (-0.0484, 3.5820) /0.056	6.0000 (0.7270, 49.5178) /0.096
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hyperbilirubinemia					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bile duct stone					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Cholecystitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cholelithiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatic cirrhosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hepatic steatosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hepatitis toxic					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hydrocholecystis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Non-alcoholic steatohepatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cardiac disorders					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cardiovascular disorder					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Atrioventricular block first degree					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Endocrine disorders					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Goitre					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypogonadism					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypothyroidism					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Congenital, familial and genetic disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gilbert's syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Keratosis follicular					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Surgical and medical procedures					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth extraction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	31 (11%)	11 (4%)	3.0418 (1.4972, 6.1801) /0.002	7.0671 (2.7880, 11.3463) /0.001	2.8182 (1.4452, 5.4954) /0.002
Investigations					
Any Event	9 (3%)	4 (1%)	2.2910 (0.6973, 7.5273) /0.172	1.7668 (-0.6972, 4.2307) /0.160	2.2500 (0.7010, 7.2221) /0.173
Lipase increased	2 (<1%)	2 (<1%)	1.0000 (0.1399, 7.1487) />0.999	<0.0001 (-1.3802, 1.3802) />0.999	1.0000 (0.1418, 7.0500) />0.999
Blood creatine phosphokinase increased	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Alanine aminotransferase increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Aspartate aminotransferase increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Blood triglycerides increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Creatinine renal clearance decreased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hepatic enzyme increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Transaminases increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Weight decreased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
General disorders and administration site conditions					
Any Event	11 (4%)	1 (<1%)	11.4044 (1.4625, 88.9328) /0.020	3.5336 (1.1779, 5.8892) /0.003	10.9999 (1.4296, 84.6361) /0.021
Injection site pain	11 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Injection site induration	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Systemic inflammatory response syndrome	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Infections and infestations					
Any Event	3 (1%)	2 (<1%)	1.5054 (0.2496, 9.0781) /0.655	0.3534 (-1.1881, 1.8949) /0.653	1.5000 (0.2526, 8.9089) /0.656
Hepatitis A	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Acute hepatitis B	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Anal abscess	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injury, poisoning and procedural complications Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Laceration	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Multiple injuries	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Post lumbar puncture syndrome	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Road traffic accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Spinal column injury	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Metabolism and nutrition disorders					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Diabetic ketoacidosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Hyperlipasaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Hypophosphataemia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Colitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Large intestine perforation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Rectal fissure	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatobiliary disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Bile duct stone	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Cholecystitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Hepatic cirrhosis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal and connective tissue disorders					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Arthritis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Vertebral foraminal stenosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Adenocarcinoma of colon	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Skin cancer	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Nervous system disorders Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Poor quality sleep	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Psychiatric disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Suicide attempt	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Skin and subcutaneous tissue disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Night sweats	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	18 (6%)	12 (4%)	1.5340 (0.7247, 3.2468) /0.263	2.1201 (-1.5672, 5.8075) /0.260	1.5000 (0.7363, 3.0559) /0.264
Infections and infestations					
Any Event	4 (1%)	4 (1%)	1.0000 (0.2476, 4.0382) />0.999	<0.0001 (-1.9450, 1.9450) />0.999	1.0000 (0.2526, 3.9593) />0.999
Hepatitis A	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Anal abscess	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Bronchitis pneumococcal	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastroenteritis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Pyelonephritis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Viral infection	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastrointestinal disorders					
Any Event	4 (1%)	1 (<1%)	4.0430 (0.4491, 36.3988) /0.213	1.0601 (-0.4792, 2.5994) /0.177	4.0000 (0.4499, 35.5660) /0.214
Anal fistula	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Colitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Enterocolitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Large intestine perforation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Rectal fissure	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Umbilical hernia	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Any Event	2 (<1%)	3 (1%)	0.6643 (0.1102, 4.0060) /0.655	-0.3534 (-1.8949, 1.1881) /0.653	0.6667 (0.1122, 3.9595) /0.656
Anogenital warts	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Adenocarcinoma of colon	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Breast cancer	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Kaposi's sarcoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injury, poisoning and procedural complications					
Any Event	1 (<1%)	2 (<1%)	0.4982 (0.0449, 5.5258) /0.570	-0.3534 (-1.5494, 0.8427) /0.563	0.5000 (0.0456, 5.4830) /0.571
Laceration	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Road traffic accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Tibia fracture	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

General disorders and administration site conditions					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Pyrexia	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Systemic inflammatory response syndrome	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Psychiatric disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Drug abuse	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Suicide attempt	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hepatobiliary disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Bile duct stone	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Cholecystitis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hydrocholecystis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Investigations Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Weight decreased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Metabolism and nutrition disorders Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diabetic ketoacidosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Musculoskeletal and connective tissue disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Arthritis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Reproductive system and breast disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Priapism	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Vascular disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Peripheral artery thrombosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral ischaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	9 (3%)	4 (1%)	2.2910 (0.6973, 7.5273) /0.172	1.7668 (-0.6972, 4.2307) /0.160	2.2500 (0.7010, 7.2221) /0.173
Infections and infestations					
Any Event	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Acute hepatitis B	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Hepatitis A	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Acute hepatitis C	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Secondary syphilis	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
General disorders and administration site conditions					
Any Event	2 (<1%)	1 (<1%)	2.0071 (0.1810, 22.2609) /0.570	0.3534 (-0.8427, 1.5494) /0.563	2.0000 (0.1824, 21.9317) /0.571
Injection site pain	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Discomfort	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Fatigue	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Diarrhoea	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Nausea	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Vomiting	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nervous system disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Amnesia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Disturbance in attention	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Dizziness	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Dysarthria	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Investigations					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Transaminases increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Adenocarcinoma of colon	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - FLAIR

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Psychiatric disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Suicide attempt	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Renal and urinary disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Renal failure	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)
Overall		239 (84%)
Age (years)	<35	120/143 (84%)
	35-<50	90/107 (84%)
	>=50	29/ 33 (88%)
Gender at Birth	Female	50/ 63 (79%)
	Male	189/220 (86%)
Race	White	189/216 (88%)
	Non-White	50/ 67 (75%)
Region	North America	39/ 47 (83%)
	Europe	187/213 (88%)
	Rest of World	13/ 23 (57%)

Note: "Any Event" represents subjects with any respective AE reported.

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Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	196/227 (86%)
	>=100,000	43/ 56 (77%)

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)
Overall		228 (81%)
Age (years)	<35	112/143 (78%)
	35-<50	88/107 (82%)
	>=50	28/ 33 (85%)
Gender at Birth	Female	50/ 63 (79%)
	Male	178/220 (81%)
Race	White	180/216 (83%)
	Non-White	48/ 67 (72%)
Region	North America	38/ 47 (81%)
	Europe	177/213 (83%)
	Rest of World	13/ 23 (57%)

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	186/227 (82%)
	>=100,000	42/ 56 (75%)

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	
Overall		11	(4%)
Age (years)	<35	8/143	(6%)
	35-<50	2/107	(2%)
	>=50	1/ 33	(3%)
Gender at Birth	Female	0/ 63	
	Male	11/220	(5%)
Race	White	9/216	(4%)
	Non-White	2/ 67	(3%)
Region	North America	1/ 47	(2%)
	Europe	10/213	(5%)
	Rest of World	0/ 23	

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	10/227 (4%)
	>=100,000	1/ 56 (2%)

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)
Overall		0
Age (years)	<35	0/143
	35-<50	0/107
	>=50	0/ 33
Gender at Birth	Female	0/ 63
	Male	0/220
Race	White	0/216
	Non-White	0/ 67
Region	North America	0/ 47
	Europe	0/213
	Rest of World	0/ 23

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	0/227
	>=100,000	0/ 56

Note: "Any Event" represents subjects with any respective AE reported.

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28NOV2019 04:28

Table 3.06
 Analysis of AESI - Proportion of Subjects with Any Adverse Event of Hepatotoxicity
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Adverse Event of Hepatotoxicity					
Any Event	3 (1%)	1 (<1%)	3.0214 (0.3124, 29.2223) /0.340	0.7067 (-0.6723, 2.0857) /0.315	3.0000 (0.3139, 28.6677) /0.340
Max Grade 1 or 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3 or 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.07
Analysis of AESI - Proportion of Subjects with Any Hypersensitivity Reaction (HSR)
Leading to Study Discontinuation by Severity (Maintenance Phase) - FLAIR

No data to report

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		12(4%)	10(4%)	1.2089 (0.5137, 2.8449) /0.664	0.7067 (-2.4774, 3.8909) /0.664	1.2000 (0.5270, 2.7324) /0.664	
Age (years)	<35	7/143(5%)	4/145(3%)	1.8143 (0.5194, 6.3381) /0.351	2.1365 (-2.2922, 6.5651) /0.344	1.7745 (0.5310, 5.9302) /0.352	0.049
	35-<50	5/107(5%)	3/109(3%)	1.7320 (0.4035, 7.4353) /0.460	1.9206 (-3.1217, 6.9630) /0.455	1.6978 (0.4161, 6.9284) /0.461	
	>=50	0/33	3/29(10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Gender at Birth	Female	0/63	3/64(5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	0.021
	Male	12/220(5%)	7/219(3%)	1.7473 (0.6747, 4.5250) /0.250	2.2582 (-1.5408, 6.0572) /0.244	1.7065 (0.6847, 4.2530) /0.251	
Race	White	8/216(4%)	7/201(3%)	1.0659 (0.3794, 2.9949) /0.904	0.2211 (-3.3520, 3.7942) /0.903	1.0635 (0.3928, 2.8794) /0.904	0.654
	Non-White	4/67(6%)	3/80(4%)	1.6296 (0.3516, 7.5525) /0.533	2.2201 (-4.8168, 9.2571) /0.536	1.5920 (0.3692, 6.8644) /0.533	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	2/47(4%)	3/62(5%)	0.8741 (0.1401, 5.4530) /0.885	-0.5834 (-8.4466, 7.2798) /0.884	0.8794 (0.1530, 5.0536) /0.885	0.915
	Europe	9/213(4%)	6/192(3%)	1.3676 (0.4777, 3.9158) /0.560	1.1004 (-2.5542, 4.7549) /0.555	1.3521 (0.4903, 3.7288) /0.560	
	Rest of World	1/23(4%)	1/29(3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	9/227(4%)	6/227(3%)	1.5206 (0.5322, 4.3446) /0.434	1.3216 (-1.9645, 4.6076) /0.431	1.5000 (0.5428, 4.1452) /0.434	0.440
	>=100,000	3/56(5%)	4/56(7%)	0.7358 (0.1570, 3.4498) /0.697	-1.7857 (-10.7455, 7.1741) /0.696	0.7500 (0.1759, 3.1986) /0.697	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		12(4%)	10(4%)	1.2089 (0.5137, 2.8449) /0.664	0.7067 (-2.4774, 3.8909) /0.664	1.2000 (0.5270, 2.7324) /0.664	
Age (years)	<35	7/143(5%)	4/145(3%)	1.8143 (0.5194, 6.3381) /0.351	2.1365 (-2.2922, 6.5651) /0.344	1.7745 (0.5310, 5.9302) /0.352	0.049
	35-<50	5/107(5%)	3/109(3%)	1.7320 (0.4035, 7.4353) /0.460	1.9206 (-3.1217, 6.9630) /0.455	1.6978 (0.4161, 6.9284) /0.461	
	>=50	0/33	3/29(10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Gender at Birth	Female	0/63	3/64(5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	0.021
	Male	12/220(5%)	7/219(3%)	1.7473 (0.6747, 4.5250) /0.250	2.2582 (-1.5408, 6.0572) /0.244	1.7065 (0.6847, 4.2530) /0.251	
Race	White	8/216(4%)	7/201(3%)	1.0659 (0.3794, 2.9949) /0.904	0.2211 (-3.3520, 3.7942) /0.903	1.0635 (0.3928, 2.8794) /0.904	0.654
	Non-White	4/67(6%)	3/80(4%)	1.6296 (0.3516, 7.5525) /0.533	2.2201 (-4.8168, 9.2571) /0.536	1.5920 (0.3692, 6.8644) /0.533	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	2/47(4%)	3/62(5%)	0.8741 (0.1401, 5.4530) /0.885	-0.5834 (-8.4466, 7.2798) /0.884	0.8794 (0.1530, 5.0536) /0.885	0.915
	Europe	9/213(4%)	6/192(3%)	1.3676 (0.4777, 3.9158) /0.560	1.1004 (-2.5542, 4.7549) /0.555	1.3521 (0.4903, 3.7288) /0.560	
	Rest of World	1/23(4%)	1/29(3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	9/227(4%)	6/227(3%)	1.5206 (0.5322, 4.3446) /0.434	1.3216 (-1.9645, 4.6076) /0.431	1.5000 (0.5428, 4.1452) /0.434	0.440
	>=100,000	3/56(5%)	4/56(7%)	0.7358 (0.1570, 3.4498) /0.697	-1.7857 (-10.7455, 7.1741) /0.696	0.7500 (0.1759, 3.1986) /0.697	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	0	NC	NC	NC	
Age (years)	<35	0/143	0/145	NC	NC	NC	NC
	35-<50	0/107	0/109	NC	NC	NC	
	>=50	0/33	0/29	NC	NC	NC	
Gender at Birth	Female	0/63	0/64	NC	NC	NC	NC
	Male	0/220	0/219	NC	NC	NC	
Race	White	0/216	0/201	NC	NC	NC	NC
	Non-White	0/67	0/80	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/47	0/62	NC	NC	NC	NC
	Europe	0/213	0/192	NC	NC	NC	
	Rest of World	0/23	0/29	NC	NC	NC	
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	0/227	0/227	NC	NC	NC	NC
	>=100,000	0/56	0/56	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	0	NC	NC	NC	
Age (years)	<35	0/143	0/145	NC	NC	NC	NC
	35-<50	0/107	0/109	NC	NC	NC	
	>=50	0/33	0/29	NC	NC	NC	
Gender at Birth	Female	0/63	0/64	NC	NC	NC	NC
	Male	0/220	0/219	NC	NC	NC	
Race	White	0/216	0/201	NC	NC	NC	NC
	Non-White	0/67	0/80	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/47	0/62	NC	NC	NC	NC
	Europe	0/213	0/192	NC	NC	NC	
	Rest of World	0/23	0/29	NC	NC	NC	
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	0/227	0/227	NC	NC	NC	NC
	>=100,000	0/56	0/56	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.09
 Analysis of AESI - Proportion of Subjects with Any Event of QT Prolongation
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of QT Prolongation					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 1 or 2	1 (<1%)	1 (<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		38(13%)	25(9%)	1.6007 (0.9382, 2.7307) /0.084	4.5936 (-0.5746, 9.7619) /0.082	1.5200 (0.9433, 2.4493) /0.085	
Age (years)	<35	18/143(13%)	12/145(8%)	1.5960 (0.7388, 3.4475) /0.234	4.3116 (-2.7360, 11.3591) /0.231	1.5210 (0.7606, 3.0414) /0.236	0.693
	35-<50	14/107(13%)	11/109(10%)	1.3412 (0.5795, 3.1039) /0.493	2.9924 (-5.5402, 11.5249) /0.492	1.2965 (0.6166, 2.7264) /0.493	
	>=50	6/33(18%)	2/29(7%)	3.0000 (0.5553, 16.2076) /0.202	11.2853 (-4.7840, 27.3546) /0.169	2.6364 (0.5763, 12.0608) /0.211	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Gender at Birth	Female	7/63(11%)	3/64(5%)	2.5417 (0.6266, 10.3100) /0.192	6.4236 (-2.9059, 15.7531) /0.177	2.3704 (0.6415, 8.7587) /0.196	0.452
	Male	31/220(14%)	22/219(10%)	1.4687 (0.8210, 2.6276) /0.195	4.0452 (-2.0366, 10.1270) /0.192	1.4027 (0.8395, 2.3437) /0.196	
Race	White	27/216(13%)	15/201(7%)	1.7714 (0.9130, 3.4371) /0.091	5.0373 (-0.6767, 10.7513) /0.084	1.6750 (0.9181, 3.0558) /0.093	0.632
	Non-White	11/67(16%)	10/80(13%)	1.3750 (0.5449, 3.4699) /0.500	3.9179 (-7.5363, 15.3721) /0.503	1.3134 (0.5946, 2.9012) /0.500	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	7/47(15%)	6/62(10%)	1.6333 (0.5103, 5.2283) /0.409	5.2162 (-7.3440, 17.7764) /0.416	1.5390 (0.5536, 4.2783) /0.409	0.656
	Europe	28/213(13%)	18/192(9%)	1.4631 (0.7814, 2.7395) /0.234	3.7705 (-2.3605, 9.9016) /0.228	1.4022 (0.8017, 2.4525) /0.236	
	Rest of World	3/23(13%)	1/29(3%)	4.2000 (0.4067, 43.3743) /0.228	9.5952 (-5.6868, 24.8772) /0.218	3.7826 (0.4208, 34.0020) /0.235	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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18NOV2019 12:05

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Any Event

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	33/227(15%)	22/227(10%)	1.5850 (0.8927, 2.8142) /0.116	4.8458 (-1.1405, 10.8322) /0.113	1.5000 (0.9033, 2.4908) /0.117	0.888
	>=100,000	5/56(9%)	3/56(5%)	1.7320 (0.3935, 7.6246) /0.468	3.5714 (-5.9448, 13.0877) /0.462	1.6667 (0.4182, 6.6421) /0.469	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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18NOV2019 12:05

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		36(13%)	24(8%)	1.5729 (0.9119, 2.7129) /0.103	4.2403 (-0.8200, 9.3005) /0.101	1.5000 (0.9194, 2.4473) /0.104	
Age (years)	<35	17/143(12%)	11/145(8%)	1.6436 (0.7411, 3.6449) /0.221	4.3019 (-2.5327, 11.1365) /0.217	1.5671 (0.7610, 3.2271) /0.223	0.631
	35-<50	13/107(12%)	11/109(10%)	1.2321 (0.5259, 2.8866) /0.631	2.0578 (-6.3265, 10.4421) /0.630	1.2039 (0.5645, 2.5675) /0.631	
	>=50	6/33(18%)	2/29(7%)	3.0000 (0.5553, 16.2076) /0.202	11.2853 (-4.7840, 27.3546) /0.169	2.6364 (0.5763, 12.0608) /0.211	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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18NOV2019 12:05

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Gender at Birth	Female	7/63(11%)	2/64(3%)	3.8750 (0.7727, 19.4339) /0.100	7.9861 (-0.8679, 16.8401) /0.077	3.5555 (0.7680, 16.4609) /0.105	0.196
	Male	29/220(13%)	22/219(10%)	1.3596 (0.7546, 2.4497) /0.307	3.1362 (-2.8500, 9.1223) /0.304	1.3122 (0.7789, 2.2107) /0.307	
Race	White	25/216(12%)	15/201(7%)	1.6230 (0.8295, 3.1756) /0.157	4.1114 (-1.4922, 9.7149) /0.150	1.5509 (0.8422, 2.8561) /0.159	0.907
	Non-White	11/67(16%)	9/80(11%)	1.5496 (0.6005, 3.9989) /0.365	5.1679 (-6.0847, 16.4205) /0.368	1.4594 (0.6434, 3.3101) /0.366	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	7/47(15%)	6/62(10%)	1.6333 (0.5103, 5.2283) /0.409	5.2162 (-7.3440, 17.7764) /0.416	1.5390 (0.5536, 4.2783) /0.409	0.647
	Europe	26/213(12%)	17/192(9%)	1.4313 (0.7508, 2.7284) /0.276	3.3524 (-2.6036, 9.3084) /0.270	1.3786 (0.7724, 2.4607) /0.277	
	Rest of World	3/23(13%)	1/29(3%)	4.2000 (0.4067, 43.3743) /0.228	9.5952 (-5.6868, 24.8772) /0.218	3.7826 (0.4208, 34.0020) /0.235	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	32/227(14%)	21/227(9%)	1.6098 (0.8975, 2.8873) /0.110	4.8458 (-1.0449, 10.7365) /0.107	1.5238 (0.9070, 2.5600) /0.112	0.865
	>=100,000	4/56(7%)	3/56(5%)	1.3590 (0.2899, 6.3712) /0.697	1.7857 (-7.1741, 10.7455) /0.696	1.3333 (0.3126, 5.6864) /0.697	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		1(<1%)	1(<1%)	1.0000 (0.0622, 16.0662) />0.999	<0.0001 (-0.9777, 0.9777) />0.999	1.0000 (0.0629, 15.9093) />0.999	
Age (years)	<35	0/143	1/145(<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
	35-<50	1/107(<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
	>=50	0/33	0/29	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Gender at Birth	Female	0/63	1/64(2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
	Male	1/220(<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Race	White	1/216(<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
	Non-White	0/67	1/80(1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/47	0/62	NC	NC	NC	NC
	Europe	1/213(<1%)	1/192(<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
	Rest of World	0/23	0/29	NC	NC	NC	
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	0/227	1/227(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
	>=100,000	1/56(2%)	0/56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	1(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Age (years)	<35	0/143	1/145(<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
	35-<50	0/107	0/109	NC	NC	NC	
	>=50	0/33	0/29	NC	NC	NC	
Gender at Birth	Female	0/63	1/64(2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
	Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Race	White	0/216	0/201	NC	NC	NC	NC
	Non-White	0/67	1/80(1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Region	North America	0/47	0/62	NC	NC	NC	NC
	Europe	0/213	1/192(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
	Rest of World	0/23	0/29	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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18NOV2019 12:05

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - FLAIR

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Induction BL (Week -20) HIV-1 RNA (c/mL)	<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
	>=100,000	0/56	0/56	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.11
 Analysis of AESI - Proportion of Subjects with Any Seizures or Seizure-like Adverse Event
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Seizures or Seizure-like Adverse Event					
Any Event	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1 or 2	3 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Weight Gain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.13
Analysis of AESI - Proportion of Subjects with Any Event of Rhabdomyolysis by Severity
(Maintenance Phase) - FLAIR

No data to report

Table 3.14
 Analysis of AESI - Proportion of Subjects with Any Event of Pancreatitis
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Pancreatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3534 (-11.1403, 11.8471) /0.952	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.15
 Analysis of AESI - Proportion of Subjects with Any Event Indicating an Impact on Creatinine
 by Severity (Maintenance Phase) - FLAIR

	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event Indicating an Impact on Creatinine					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1 or 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.16
Analysis of AESI - Proportion of Subjects with Any Event of Relevance to Safety in Pregnancy
by Severity (Maintenance Phase) - FLAIR

No data to report

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
with no covariate adjustment.
NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	132/143 (92%)	111/145 (77%)	3.6757 (1.7799, 7.5908) /<.001	15.7560 (7.5933, 23.9186) /<.001	1.2058 (1.0892, 1.3350) /<.001	NC
35-<50	102/107 (95%)	90/109 (83%)	4.3067 (1.5451, 12.0042) /0.005	12.7583 (4.5903, 20.9263) /0.002	1.1545 (1.0489, 1.2707) /0.003	
>=50	33/ 33 (100%)	24/ 29 (83%)	>999 (<0.0001, -) />0.999	NC	1.1830 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	104/143 (73%)	89/145 (61%)	1.6779 (1.0206, 2.7586) /0.041	11.3480 (0.5737, 22.1222) /0.039	1.1849 (1.0061, 1.3954) /0.042	0.213
35-<50	72/107 (67%)	63/109 (58%)	1.5020 (0.8626, 2.6155) /0.151	9.4916 (-3.3531, 22.3362) /0.148	1.1642 (0.9458, 1.4331) /0.152	
>=50	20/ 33 (61%)	21/ 29 (72%)	0.5861 (0.2005, 1.7133) /0.329	-11.8077 (-35.1002, 11.4847) /0.320	0.8369 (0.5868, 1.1938) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
<35	27/143 (19%)	22/145 (15%)	1.3013 (0.7018, 2.4129) /0.403	3.7087 (-4.9655, 12.3829) /0.402	1.2444 (0.7448, 2.0793) /0.404	0.928
35-<50	22/107 (21%)	20/109 (18%)	1.1518 (0.5867, 2.2611) /0.681	2.2121 (-8.3444, 12.7686) /0.681	1.1206 (0.6506, 1.9299) /0.682	
>=50	7/ 33 (21%)	6/ 29 (21%)	1.0321 (0.3028, 3.5178) /0.960	0.5225 (-19.7731, 20.8180) /0.960	1.0253 (0.3888, 2.7035) /0.960	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<35	18/143 (13%)	16/145 (11%)	1.1610 (0.5668, 2.3779) /0.683	1.5529 (-5.9013, 9.0071) /0.683	1.1407 (0.6060, 2.1474) /0.683	0.419
35-<50	16/107 (15%)	8/109 (7%)	2.2198 (0.9073, 5.4310) /0.081	7.6138 (-0.7303, 15.9580) /0.074	2.0374 (0.9103, 4.5601) /0.083	
>=50	4/ 33 (12%)	4/ 29 (14%)	0.8621 (0.1952, 3.8081) /0.845	-1.6719 (-18.4500, 15.1062) /0.845	0.8788 (0.2412, 3.2021) /0.845	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <35	16/143 (11%)	13/145 (9%)	1.2792 (0.5915, 2.7665) /0.531	2.2233 (-4.7277, 9.1743) /0.531	1.2480 (0.6232, 2.4992) /0.532	0.957
35-<50	8/107 (7%)	6/109 (6%)	1.3872 (0.4646, 4.1419) /0.558	1.9720 (-4.5981, 8.5422) /0.556	1.3583 (0.4877, 3.7831) /0.558	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	11/143 (8%)	5/145 (3%)	2.3333 (0.7896, 6.8953) /0.125	4.2440 (-1.0375, 9.5256) /0.115	2.2308 (0.7951, 6.2584) /0.127	0.179
35-<50	4/107 (4%)	5/109 (5%)	0.8078 (0.2109, 3.0933) /0.755	-0.8488 (-6.1728, 4.4751) /0.755	0.8150 (0.2249, 2.9530) /0.755	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<35	9/143 (6%)	4/145 (3%)	2.3675 (0.7122, 7.8707) /0.160	3.5351 (-1.2555, 8.3257) /0.148	2.2815 (0.7189, 7.2408) /0.162	0.154
35-<50	3/107 (3%)	7/109 (6%)	0.4203 (0.1058, 1.6704) /0.218	-3.6183 (-9.1827, 1.9462) /0.202	0.4366 (0.1159, 1.6441) /0.221	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis <35	9/143 (6%)	4/145 (3%)	2.3675 (0.7122, 7.8707) /0.160	3.5351 (-1.2555, 8.3257) /0.148	2.2815 (0.7189, 7.2408) /0.162	0.201
35-<50	4/107 (4%)	5/109 (5%)	0.8078 (0.2109, 3.0933) /0.755	-0.8488 (-6.1728, 4.4751) /0.755	0.8150 (0.2249, 2.9530) /0.755	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.326
35-<50	5/107 (5%)	5/109 (5%)	1.0196 (0.2865, 3.6282) /0.976	0.0857 (-5.5194, 5.6909) /0.976	1.0187 (0.3036, 3.4181) /0.976	
>=50	3/ 33 (9%)	4/ 29 (14%)	0.6250 (0.1277, 3.0595) /0.562	-4.7022 (-20.6306, 11.2262) /0.563	0.6591 (0.1607, 2.7033) /0.563	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis <35	5/143 (3%)	4/145 (3%)	1.2772 (0.3359, 4.8560) /0.720	0.7379 (-3.2834, 4.7592) /0.719	1.2675 (0.3474, 4.6245) /0.720	0.889
35-<50	4/107 (4%)	5/109 (5%)	0.8078 (0.2109, 3.0933) /0.755	-0.8488 (-6.1728, 4.4751) /0.755	0.8150 (0.2249, 2.9530) /0.755	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <35	6/143 (4%)	2/145 (1%)	3.1314 (0.6213, 15.7814) /0.167	2.8165 (-0.9785, 6.6115) /0.146	3.0420 (0.6244, 14.8210) /0.169	0.477
35-<50	5/107 (5%)	4/109 (4%)	1.2868 (0.3360, 4.9276) /0.713	1.0032 (-4.3308, 6.3371) /0.712	1.2734 (0.3514, 4.6140) /0.713	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <35	6/143 (4%)	2/145 (1%)	3.1314 (0.6213, 15.7814) /0.167	2.8165 (-0.9785, 6.6115) /0.146	3.0420 (0.6244, 14.8210) /0.169	0.988
35-<50	5/107 (5%)	2/109 (2%)	2.6225 (0.4976, 13.8218) /0.256	2.8380 (-1.8885, 7.5646) /0.239	2.5467 (0.5050, 12.8430) /0.257	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
<35	7/143 (5%)	4/145 (3%)	1.8143 (0.5194, 6.3381) /0.351	2.1365 (-2.2922, 6.5651) /0.344	1.7745 (0.5310, 5.9302) /0.352	0.640
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.176
35-<50	3/107 (3%)	5/109 (5%)	0.6000 (0.1398, 2.5757) /0.492	-1.7834 (-6.8042, 3.2374) /0.486	0.6112 (0.1498, 2.4942) /0.493	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
<35	5/143 (3%)	5/145 (3%)	1.0145 (0.2873, 3.5826) /0.982	0.0482 (-4.1808, 4.2773) /0.982	1.0140 (0.3000, 3.4273) /0.982	0.277
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<35	2/143 (1%)	4/145 (3%)	0.5000 (0.0901, 2.7738) /0.428	-1.3600 (-4.6481, 1.9280) /0.418	0.5070 (0.0943, 2.7246) /0.429	0.058
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	3/ 29 (10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	1/143 (<1%)	3/145 (2%)	0.3333 (0.0343, 3.2429) /0.344	-1.3697 (-4.0591, 1.3198) /0.318	0.3380 (0.0356, 3.2112) /0.345	NC
35-<50	0/107	3/109 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0095 (-24.7142, 14.6951) /0.618	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	4/ 29 (14%)	0.1953 (0.0205, 1.8584) /0.155	-10.7628 (-24.6089, 3.0833) /0.128	0.2197 (0.0260, 1.8557) /0.164	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
<35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	0.261
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.684
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <35	2/143 (1%)	5/145 (3%)	0.3972 (0.0758, 2.0813) /0.275	-2.0497 (-5.5887, 1.4894) /0.256	0.4056 (0.0800, 2.0566) /0.276	0.556
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<35	5/143 (3%)	2/145 (1%)	2.5906 (0.4943, 13.5758) /0.260	2.1172 (-1.4420, 5.6764) /0.244	2.5350 (0.4999, 12.8540) /0.261	0.283
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.151
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
<35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	0.072
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<35	4/143 (3%)	2/145 (1%)	2.0576 (0.3709, 11.4144) /0.409	1.4179 (-1.8848, 4.7206) /0.400	2.0280 (0.3774, 10.8985) /0.410	0.917
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	0.289
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis <35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
<35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.121
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.740
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.970
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal <35	3/143 (2%)	4/145 (3%)	0.7554 (0.1660, 3.4368) /0.717	-0.6607 (-4.2138, 2.8923) /0.716	0.7605 (0.1733, 3.3375) /0.717	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
<35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	0.972
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.567
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	>0.999
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotons illitis						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.448
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
<35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
<35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	0.216
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	0.403
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Acute hepatitis B						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanitis candida						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma infection						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Onychomycosis						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Otitis media						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Abscess limb <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vulvovaginitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis pneumococcal						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cat scratch disease						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis bacterial						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dacryocystitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Gastroenteritis shigella						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Genital infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary chlamydia infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract gonococcal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter gastritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hepatitis E						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes virus infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Impetigo						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infectious colitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Lice infestation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphogranuloma venereum						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Malaria						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma genitalium infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Oophoritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Pertussis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis mycoplasmal <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis chronic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection bacterial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Skin candida						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Staphylococcal abscess						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidi asis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tinea cruris						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection bacterial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urethritis mycoplasmal						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Vaginal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Viral tonsillitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal mycotic infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	120/143 (84%)	14/145 (10%)	48.8198 (24.0249, 99.2043) /<.001	74.2609 (66.5559, 81.9659) /<.001	8.6913 (5.2556, 14.3731) /<.001	NC
35-<50	92/107 (86%)	8/109 (7%)	77.4333 (31.3763, 191.0973) /<.001	78.6419 (70.4418, 86.8419) /<.001	11.7150 (5.9862, 22.9261) /<.001	
>=50	31/ 33 (94%)	4/ 29 (14%)	96.8750 (16.3816, 572.8858) /<.001	80.1463 (65.1869, 95.1056) /<.001	6.8106 (2.7305, 16.9876) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	116/143 (81%)	0/145	>999 (>999, >999) /NC	NC	NC	NC
35-<50	86/107 (80%)	0/109	>999 (>999, >999) /NC	NC	NC	
>=50	25/ 33 (76%)	0/ 29	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<35	24/143 (17%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	15/107 (14%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
<35	17/143 (12%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	16/107 (15%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	12/143 (8%)	4/145 (3%)	3.2290 (1.0160, 10.2624) /0.047	5.6330 (0.3644, 10.9015) /0.036	3.0420 (1.0048, 9.2097) /0.049	NC
35-<50	8/107 (7%)	0/109	>999 (>999, >999) /NC	9.5359 (-10.2331, 29.3049) /0.344	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
<35	12/143 (8%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	7/107 (7%)	0/109	>999 (>999, >999) /NC	8.6442 (-11.0734, 28.3618) /0.390	>999 (>999, >999) /NC	
>=50	4/ 33 (12%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
<35	5/143 (3%)	0/145	>999 (>999, >999) /NC	5.7283 (-11.2366, 22.6932) /0.508	>999 (>999, >999) /NC	NC
35-<50	6/107 (6%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	4/143 (3%)	4/145 (3%)	1.0144 (0.2488, 4.1365) /0.984	0.0386 (-3.7576, 3.8347) /0.984	1.0140 (0.2586, 3.9765) /0.984	0.553
35-<50	1/107 (<1%)	3/109 (3%)	0.3333 (0.0341, 3.2561) /0.345	-1.8177 (-5.3894, 1.7540) /0.319	0.3396 (0.0359, 3.2133) /0.346	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.948
35-<50	3/107 (3%)	3/109 (3%)	1.0192 (0.2011, 5.1658) /0.982	0.0514 (-4.3322, 4.4351) /0.982	1.0187 (0.2103, 4.9354) /0.982	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	6/107 (6%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	4/ 33 (12%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
<35	8/143 (6%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pain						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Chest pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haemorrhage						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catheter site erythema						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chills						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cyst						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site granuloma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site necrosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site scar						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Oedema peripheral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Swelling						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site bruise						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	55/143 (38%)	37/145 (26%)	1.8243 (1.1033, 3.0165) /0.019	12.9443 (2.2703, 23.6183) /0.017	1.5073 (1.0655, 2.1322) /0.020	0.865
35-<50	41/107 (38%)	30/109 (28%)	1.6359 (0.9222, 2.9019) /0.092	10.7948 (-1.6613, 23.2510) /0.089	1.3922 (0.9444, 2.0523) /0.095	
>=50	11/ 33 (33%)	8/ 29 (28%)	1.3125 (0.4415, 3.9017) /0.625	5.7471 (-17.1286, 28.6228) /0.622	1.2083 (0.5640, 2.5887) /0.626	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	13/143 (9%)	14/145 (10%)	0.9357 (0.4234, 2.0678) /0.870	-0.5643 (-7.2956, 6.1671) /0.869	0.9416 (0.4589, 1.9319) /0.870	0.319
35-<50	16/107 (15%)	8/109 (7%)	2.2198 (0.9073, 5.4310) /0.081	7.6138 (-0.7303, 15.9580) /0.074	2.0374 (0.9103, 4.5601) /0.083	
>=50	3/ 33 (9%)	3/ 29 (10%)	0.8667 (0.1608, 4.6701) /0.868	-1.2539 (-16.0546, 13.5468) /0.868	0.8788 (0.1921, 4.0203) /0.868	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	10/143 (7%)	7/145 (5%)	1.4823 (0.5481, 4.0084) /0.438	2.1654 (-3.2792, 7.6101) /0.436	1.4486 (0.5671, 3.7003) /0.439	0.915
35-<50	5/107 (5%)	3/109 (3%)	1.7320 (0.4035, 7.4353) /0.460	1.9206 (-3.1217, 6.9630) /0.455	1.6978 (0.4161, 6.9284) /0.461	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
<35	5/143 (3%)	2/145 (1%)	2.5906 (0.4943, 13.5758) /0.260	2.1172 (-1.4420, 5.6764) /0.244	2.5350 (0.4999, 12.8540) /0.261	0.400
35-<50	6/107 (6%)	6/109 (6%)	1.0198 (0.3183, 3.2674) /0.974	0.1029 (-6.0073, 6.2131) /0.974	1.0187 (0.3392, 3.0594) /0.974	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
<35	10/143 (7%)	1/145 (<1%)	10.8271 (1.3675, 85.7251) /0.024	6.3034 (1.9117, 10.6950) /0.005	10.1399 (1.3150, 78.1853) /0.026	0.380
35-<50	5/107 (5%)	1/109 (<1%)	5.2941 (0.6081, 46.0909) /0.131	3.7555 (-0.6259, 8.1368) /0.093	5.0935 (0.6051, 42.8779) /0.134	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache <35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.995
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <35	6/143 (4%)	3/145 (2%)	2.0730 (0.5083, 8.4539) /0.309	2.1268 (-1.8939, 6.1476) /0.300	2.0280 (0.5171, 7.9530) /0.311	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation <35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.272
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.361
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.137
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
<35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.403
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.078
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
<35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	>0.999
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.711
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal 1 haemorrhage						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal inflammation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea haemorrhagic						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroduodenitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival bleeding						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Stomatitis <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Aerophagia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal pruritus						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal ulcer						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Aphthous ulcer						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Barrett's oesophagus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile acid malabsorption						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bowel movement irregularity						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Colitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis microscopic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dysbacteriosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enterocolitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal sounds abnormal						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival swelling						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Haematochezi ^a						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal polyp						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Oral pain						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Palatal ulcer						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Pancreatitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia oral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth development disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	29/143 (20%)	14/145 (10%)	2.3803 (1.1993, 4.7243) /0.013	10.6245 (2.4674, 18.7817) /0.011	2.1004 (1.1590, 3.8064) /0.014	0.036
35-<50	25/107 (23%)	17/109 (16%)	1.6499 (0.8323, 3.2707) /0.152	7.7682 (-2.7521, 18.2884) /0.148	1.4981 (0.8596, 2.6106) /0.154	
>=50	10/ 33 (30%)	13/ 29 (45%)	0.5351 (0.1887, 1.5177) /0.240	-14.5246 (-38.4719, 9.4227) /0.235	0.6760 (0.3507, 1.3031) /0.242	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <35	12/143 (8%)	4/145 (3%)	3.2290 (1.0160, 10.2624) /0.047	5.6330 (0.3644, 10.9015) /0.036	3.0420 (1.0048, 9.2097) /0.049	0.203
35-<50	6/107 (6%)	4/109 (4%)	1.5594 (0.4274, 5.6894) /0.501	1.9378 (-3.6713, 7.5468) /0.498	1.5280 (0.4436, 5.2630) /0.502	
>=50	4/ 33 (12%)	5/ 29 (17%)	0.6621 (0.1598, 2.7437) /0.570	-5.1202 (-22.8122, 12.5718) /0.571	0.7030 (0.2083, 2.3729) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia <35	7/143 (5%)	2/145 (1%)	3.6801 (0.7513, 18.0266) /0.108	3.5158 (-0.4979, 7.5295) /0.086	3.5490 (0.7500, 16.7945) /0.110	0.883
35-<50	5/107 (5%)	2/109 (2%)	2.6225 (0.4976, 13.8218) /0.256	2.8380 (-1.8885, 7.5646) /0.239	2.5467 (0.5050, 12.8430) /0.257	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.316
35-<50	3/107 (3%)	5/109 (5%)	0.6000 (0.1398, 2.5757) /0.492	-1.7834 (-6.8042, 3.2374) /0.486	0.6112 (0.1498, 2.4942) /0.493	
>=50	4/ 33 (12%)	1/ 29 (3%)	3.8621 (0.4062, 36.7155) /0.240	8.6729 (-4.2924, 21.6383) /0.190	3.5151 (0.4162, 29.6910) /0.248	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.830
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.933
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteochondro sis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.568
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tendonitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal stiffness						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

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Plantar fasciitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthritis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
<hr/>						
Bursitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Intervertebral disc disorder <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Osteoporosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue mass						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	35/143 (24%)	16/145 (11%)	2.6128 (1.3717, 4.9768) /0.003	13.4410 (4.7425, 22.1396) /0.002	2.2181 (1.2868, 3.8235) /0.004	0.771
35-<50	21/107 (20%)	13/109 (12%)	1.8032 (0.8514, 3.8190) /0.124	7.6996 (-1.9778, 17.3769) /0.119	1.6456 (0.8693, 3.1151) /0.126	
>=50	8/ 33 (24%)	4/ 29 (14%)	2.0000 (0.5332, 7.5023) /0.304	10.4493 (-8.8197, 29.7184) /0.288	1.7576 (0.5900, 5.2361) /0.311	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	18/143 (13%)	11/145 (8%)	1.7542 (0.7972, 3.8601) /0.163	5.0012 (-1.9364, 11.9389) /0.158	1.6592 (0.8128, 3.3872) /0.164	0.909
35-<50	16/107 (15%)	8/109 (7%)	2.2198 (0.9073, 5.4310) /0.081	7.6138 (-0.7303, 15.9580) /0.074	2.0374 (0.9103, 4.5601) /0.083	
>=50	5/ 33 (15%)	2/ 29 (7%)	2.4107 (0.4304, 13.5022) /0.317	8.2550 (-7.0652, 23.5751) /0.291	2.1970 (0.4607, 10.4769) /0.323	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness <35	9/143 (6%)	2/145 (1%)	4.8022 (1.0191, 22.6297) /0.047	4.9144 (0.5046, 9.3242) /0.029	4.5629 (1.0033, 20.7517) /0.050	NC
35-<50	6/107 (6%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia <35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Somnolence <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Anosmia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical neuritis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nerve compression						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tremor						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Trigeminal neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Visual field defect						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	26/143 (18%)	17/145 (12%)	1.6732 (0.8642, 3.2397) /0.127	6.4577 (-1.7509, 14.6663) /0.123	1.5508 (0.8805, 2.7313) /0.129	0.270
35-<50	19/107 (18%)	11/109 (10%)	1.9236 (0.8674, 4.2656) /0.107	7.6653 (-1.5221, 16.8526) /0.102	1.7596 (0.8799, 3.5186) /0.110	
>=50	2/ 33 (6%)	4/ 29 (14%)	0.4032 (0.0682, 2.3845) /0.317	-7.7325 (-22.6919, 7.2269) /0.311	0.4394 (0.0867, 2.2257) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
<35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.103
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	0/ 33	3/ 29 (10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema <35	3/143 (2%)	3/145 (2%)	1.0143 (0.2013, 5.1111) /0.986	0.0289 (-3.2704, 3.3282) /0.986	1.0140 (0.2081, 4.9403) /0.986	0.965
35-<50	4/107 (4%)	3/109 (3%)	1.3722 (0.2997, 6.2821) /0.684	0.9860 (-3.7418, 5.7138) /0.683	1.3583 (0.3114, 5.9251) /0.684	
>=50	0/ 33	0/ 29	NC	NC	NC	
Acne <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
<35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosi s						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dyshidrotic eczema						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Night sweats						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Papule <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
<hr/>						
Pityriasis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin mass <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Urticaria <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Blood blister <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dermatitis allergic						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ephelides						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Granuloma annulare						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipodystrophy acquired						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail pigmentation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pityriasis alba						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Pruritus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Psoriasis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Purpura <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rash macular						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash morbilliform						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rash papular						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin erosion <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin hyperpigmentation <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hypopigmentation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin induration						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin reaction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xeroderma <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	24/143 (17%)	19/145 (13%)	1.3375 (0.6969, 2.5669) /0.382	3.6798 (-4.5473, 11.9068) /0.381	1.2808 (0.7347, 2.2329) /0.383	0.878
35-<50	16/107 (15%)	12/109 (11%)	1.4212 (0.6378, 3.1670) /0.390	3.9441 (-5.0105, 12.8987) /0.388	1.3583 (0.6749, 2.7334) /0.391	
>=50	3/ 33 (9%)	3/ 29 (10%)	0.8667 (0.1608, 4.6701) /0.868	-1.2539 (-16.0546, 13.5468) /0.868	0.8788 (0.1921, 4.0203) /0.868	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough <35	5/143 (3%)	6/145 (4%)	0.8394 (0.2503, 2.8147) /0.777	-0.6414 (-5.0656, 3.7827) /0.776	0.8450 (0.2638, 2.7066) /0.777	0.992
35-<50	3/107 (3%)	4/109 (4%)	0.7572 (0.1654, 3.4667) /0.720	-0.8660 (-5.5821, 3.8502) /0.719	0.7640 (0.1751, 3.3329) /0.720	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<35	6/143 (4%)	4/145 (3%)	1.5438 (0.4263, 5.5904) /0.508	1.4372 (-2.7943, 5.6686) /0.506	1.5210 (0.4384, 5.2764) /0.509	NC
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
<35	8/143 (6%)	1/145 (<1%)	8.5333 (1.0533, 69.1345) /0.045	4.9048 (0.9045, 8.9050) /0.016	8.1119 (1.0277, 64.0275) /0.047	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh <35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	0.424
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
<35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea <35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Sinus congestion						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchial obstruction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Bronchitis chronic						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bronchospasm						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Nasal dryness						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal obstruction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal turbinate hypertrophy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Reflux laryngitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Throat irritation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tonsillar hypertrophy						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	17/143 (12%)	14/145 (10%)	1.2625 (0.5973, 2.6685) /0.542	2.2329 (-4.9259, 9.3917) /0.541	1.2313 (0.6309, 2.4028) /0.542	0.136
35-<50	8/107 (7%)	18/109 (17%)	0.4085 (0.1694, 0.9850) /0.046	-9.0371 (-17.6059, -0.4684) /0.039	0.4528 (0.2057, 0.9966) /0.049	
>=50	6/ 33 (18%)	5/ 29 (17%)	1.0667 (0.2884, 3.9454) /0.923	0.9404 (-18.0905, 19.9714) /0.923	1.0545 (0.3592, 3.0956) /0.923	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
<35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	0.784
35-<50	1/107 (<1%)	4/109 (4%)	0.2476 (0.0272, 2.2526) /0.215	-2.7351 (-6.7079, 1.2376) /0.177	0.2547 (0.0289, 2.2417) /0.218	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	5/143 (3%)	0/145	>999 (>999, >999) /NC	5.7283 (-11.2366, 22.6932) /0.508	>999 (>999, >999) /NC	0.058
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.225
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	0.449
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ankle fracture						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cranio-cerebral injury						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure via inhalation						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Fracture						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Heat stroke <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Joint dislocation <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Joint injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
<hr/>						
Neck injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile contusion						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin injury						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tendon injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tibia fracture						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Traumatic haematoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral injury						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	20/143 (14%)	12/145 (8%)	1.8022 (0.8458, 3.8401) /0.127	5.7102 (-1.5305, 12.9508) /0.122	1.6900 (0.8584, 3.3271) /0.129	0.769
35-<50	15/107 (14%)	10/109 (9%)	1.6141 (0.6906, 3.7727) /0.269	4.8444 (-3.6785, 13.3673) /0.265	1.5280 (0.7186, 3.2491) /0.271	
>=50	6/ 33 (18%)	5/ 29 (17%)	1.0667 (0.2884, 3.9454) /0.923	0.9404 (-18.0905, 19.9714) /0.923	1.0545 (0.3592, 3.0956) /0.923	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	7/143 (5%)	6/145 (4%)	1.1924 (0.3907, 3.6390) /0.757	0.7572 (-4.0402, 5.5546) /0.757	1.1830 (0.4075, 3.4340) /0.757	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<35	6/143 (4%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	3/107 (3%)	3/109 (3%)	1.0192 (0.2011, 5.1658) /0.982	0.0514 (-4.3322, 4.4351) /0.982	1.0187 (0.2103, 4.9354) /0.982	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	3/109 (3%)	0.6730 (0.1102, 4.1101) /0.668	-0.8831 (-4.8854, 3.1191) /0.665	0.6791 (0.1158, 3.9839) /0.668	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose abnormal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Aortic bruit						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood folate decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin decreased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heart rate increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma test positive						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Platelet count decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Protein urine present						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Total lung capacity decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Treponema test positive						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Weight increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	18/143 (13%)	13/145 (9%)	1.4621 (0.6878, 3.1082) /0.323	3.6219 (-3.5322, 10.7759) /0.321	1.4040 (0.7149, 2.7573) /0.324	0.922
35-<50	14/107 (13%)	11/109 (10%)	1.3412 (0.5795, 3.1039) /0.493	2.9924 (-5.5402, 11.5249) /0.492	1.2965 (0.6166, 2.7264) /0.493	
>=50	6/ 33 (18%)	3/ 29 (10%)	1.9259 (0.4354, 8.5187) /0.388	7.8370 (-9.3684, 25.0424) /0.372	1.7576 (0.4824, 6.4041) /0.393	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	5/143 (3%)	3/145 (2%)	1.7150 (0.4021, 7.3141) /0.466	1.4275 (-2.3714, 5.2265) /0.461	1.6900 (0.4115, 6.9400) /0.467	0.620
35-<50	7/107 (7%)	2/109 (2%)	3.7450 (0.7599, 18.4554) /0.105	4.7072 (-0.6124, 10.0268) /0.083	3.5654 (0.7578, 16.7760) /0.108	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia <35	4/143 (3%)	2/145 (1%)	2.0576 (0.3709, 11.4144) /0.409	1.4179 (-1.8848, 4.7206) /0.400	2.0280 (0.3774, 10.8985) /0.410	0.247
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.145
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	3/ 33 (9%)	0/ 29	>999 (>999, >999) /NC	11.0748 (-27.1430, 49.2927) /0.570	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	1/109 (<1%)	4.1942 (0.4611, 38.1515) /0.203	2.8209 (-1.1945, 6.8362) /0.169	4.0748 (0.4629, 35.8673) /0.206	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.436
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Affective disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Drug abuse						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Paranoia <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	15/143 (10%)	12/145 (8%)	1.2988 (0.5854, 2.8818) /0.520	2.2136 (-4.5193, 8.9466) /0.519	1.2675 (0.6150, 2.6120) /0.521	0.302
35-<50	12/107 (11%)	10/109 (9%)	1.2505 (0.5160, 3.0305) /0.621	2.0406 (-6.0287, 10.1100) /0.620	1.2224 (0.5516, 2.7089) /0.621	
>=50	6/ 33 (18%)	1/ 29 (3%)	6.2222 (0.7020, 55.1545) /0.101	14.7335 (-0.0066, 29.4737) /0.050	5.2727 (0.6738, 41.2614) /0.113	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<35	11/143 (8%)	9/145 (6%)	1.2593 (0.5054, 3.1375) /0.621	1.4854 (-4.3881, 7.3589) /0.620	1.2393 (0.5296, 2.8999) /0.621	0.187
35-<50	9/107 (8%)	4/109 (4%)	2.4107 (0.7192, 8.0805) /0.154	4.7415 (-1.5922, 11.0752) /0.142	2.2921 (0.7278, 7.2184) /0.156	
>=50	3/ 33 (9%)	0/ 29	>999 (>999, >999) /NC	11.0748 (-27.1430, 49.2927) /0.570	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	3/109 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0095 (-24.7142, 14.6951) /0.618	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypovitaminosis						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasae mia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Diabetic ketoacidosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glucose tolerance impaired						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypocalcaemi ^a						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypokalaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
<hr/>						
Hypomagnesaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	7/143 (5%)	13/145 (9%)	0.5226 (0.2022, 1.3507) /0.180	-4.0704 (-9.9124, 1.7716) /0.172	0.5460 (0.2244, 1.3287) /0.182	0.018
35-<50	14/107 (13%)	4/109 (4%)	3.9516 (1.2566, 12.4264) /0.019	9.4144 (2.1146, 16.7141) /0.011	3.5654 (1.2124, 10.4854) /0.021	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital warts						
<35	5/143 (3%)	6/145 (4%)	0.8394 (0.2503, 2.8147) /0.777	-0.6414 (-5.0656, 3.7827) /0.776	0.8450 (0.2638, 2.7066) /0.777	NC
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral papilloma						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Uterine leiomyoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Adenocarcinoma of colon						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal neoplasm						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign spleen tumour						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dysplastic naevus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kaposi's sarcoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kidney angiomyolipoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neoplasm skin						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral fibroma <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin cancer <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reproductive system and breast disorders						
Any Event						
<35	10/143 (7%)	7/145 (5%)	1.4823 (0.5481, 4.0084) /0.438	2.1654 (-3.2792, 7.6101) /0.436	1.4486 (0.5671, 3.7003) /0.439	0.600
35-<50	7/107 (7%)	8/109 (7%)	0.8838 (0.3088, 2.5290) /0.818	-0.7974 (-7.5737, 5.9789) /0.818	0.8914 (0.3350, 2.3718) /0.818	
>=50	2/ 33 (6%)	3/ 29 (10%)	0.5591 (0.0867, 3.6046) /0.541	-4.2842 (-18.0367, 9.4683) /0.541	0.5859 (0.1051, 3.2660) /0.542	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.917
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrophic vulvovaginitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital lesion						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Breast pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe						
a						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menopausal symptoms						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Menstruation irregular						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Penile pain						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polymenorrhoea						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Priapism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular pain						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal dysplasia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal ulceration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Varicocele						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvar dysplasia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	6/143 (4%)	6/145 (4%)	1.0146 (0.3194, 3.2233) /0.980	0.0579 (-4.5581, 4.6739) /0.980	1.0140 (0.3349, 3.0699) /0.980	0.656
35-<50	8/107 (7%)	4/109 (4%)	2.1212 (0.6192, 7.2661) /0.231	3.8069 (-2.3000, 9.9138) /0.222	2.0374 (0.6322, 6.5658) /0.233	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.867
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	0.364
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
<35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypochromic anaemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Leukocytosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Normocytic anaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splenomegaly <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	8/143 (6%)	3/145 (2%)	2.8049 (0.7289, 10.7945) /0.134	3.5254 (-0.8967, 7.9476) /0.118	2.7040 (0.7320, 9.9878) /0.136	0.318
35-<50	4/107 (4%)	4/109 (4%)	1.0194 (0.2483, 4.1851) /0.979	0.0686 (-4.9691, 5.1062) /0.979	1.0187 (0.2615, 3.9690) /0.979	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
<35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Calculus urinary						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Glomerulonephritis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition urgency						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nephrolithiasis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Nephropathy <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pollakiuria <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral caruncle						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary incontinence						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
<35	6/143 (4%)	4/145 (3%)	1.5438 (0.4263, 5.5904) /0.508	1.4372 (-2.7943, 5.6686) /0.506	1.5210 (0.4384, 5.2764) /0.509	0.330
35-<50	6/107 (6%)	3/109 (3%)	2.0990 (0.5112, 8.6185) /0.304	2.8552 (-2.4773, 8.1877) /0.294	2.0374 (0.5229, 7.9380) /0.305	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Blepharitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Asthenopia <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Astigmatism <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Blepharospasm <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cataract <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Chalazion <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chorioretinal disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic retinopathy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dry eye						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Eye irritation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Eye pruritus <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glare <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Glaucoma <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meibomian gland dysfunction						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Myopia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uveitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Vitreous detachment <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	8/143 (6%)	2/145 (1%)	4.2370 (0.8839, 20.3096) /0.071	4.2151 (-0.0029, 8.4331) /0.050	4.0559 (0.8763, 18.7718) /0.073	0.095
35-<50	2/107 (2%)	3/109 (3%)	0.6730 (0.1102, 4.1101) /0.668	-0.8831 (-4.8854, 3.1191) /0.665	0.6791 (0.1158, 3.9839) /0.668	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo <35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	0.832
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.517
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Noninfective myringitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.020
35-<50	7/107 (7%)	0/109	>999 (>999, >999) /NC	8.6442 (-11.0734, 28.3618) /0.390	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Circulatory collapse						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hot flush						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperaemia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hypertensive crisis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intermittent claudication						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	7/143 (5%)	1/145 (<1%)	7.4118 (0.9001, 61.0335) /0.063	4.2054 (0.4212, 7.9897) /0.029	7.0979 (0.8845, 56.9582) /0.065	0.521
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mite allergy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbilirubinaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Cholecystitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hepatic cirrhosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatic steatosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hepatitis toxic						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocholecystis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrioventricular block first degree						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Goitre						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Hypogonadism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Keratosis follicular						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth extraction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	57/ 63 (90%)	50/ 64 (78%)	2.6600 (0.9506, 7.4434) /0.062	12.3512 (-0.1035, 24.8059) /0.052	1.1581 (0.9944, 1.3487) /0.059	0.721
Male	210/220 (95%)	175/219 (80%)	5.2800 (2.5821, 10.7969) /<.001	15.5459 (9.5678, 21.5240) /<.001	1.1945 (1.1111, 1.2842) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	38/ 63 (60%)	36/ 64 (56%)	1.1822 (0.5835, 2.3954) /0.642	4.0675 (-13.0691, 21.2040) /0.642	1.0723 (0.7987, 1.4397) /0.642	0.679
Male	158/220 (72%)	137/219 (63%)	1.5253 (1.0210, 2.2788) /0.039	9.2611 (0.5188, 18.0034) /0.038	1.1480 (1.0064, 1.3097) /0.040	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
Female	10/ 63 (16%)	8/ 64 (13%)	1.3208 (0.4846, 3.5999) /0.587	3.3730 (-8.7544, 15.5004) /0.586	1.2698 (0.5362, 3.0073) /0.587	0.829
Male	46/220 (21%)	40/219 (18%)	1.1830 (0.7377, 1.8973) /0.485	2.6443 (-4.7761, 10.0647) /0.485	1.1448 (0.7827, 1.6743) /0.486	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	8/ 63 (13%)	7/ 64 (11%)	1.1844 (0.4023, 3.4874) /0.759	1.7609 (-9.4670, 12.9888) /0.759	1.1610 (0.4477, 3.0106) /0.759	0.715
Male	30/220 (14%)	21/219 (10%)	1.4887 (0.8235, 2.6913) /0.188	4.0473 (-1.9336, 10.0282) /0.185	1.4221 (0.8410, 2.4048) /0.189	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
Female	4/ 63 (6%)	0/ 64	>999 (>999, >999) /NC	8.4601 (-17.2551, 34.1754) /0.519	>999 (>999, >999) /NC	0.022
Male	21/220 (10%)	20/219 (9%)	1.0500 (0.5519, 1.9975) /0.882	0.4130 (-5.0306, 5.8566) /0.882	1.0452 (0.5834, 1.8726) /0.882	
Gastroenteritis						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.746
Male	13/220 (6%)	9/219 (4%)	1.4654 (0.6131, 3.5023) /0.390	1.7995 (-2.2773, 5.8763) /0.387	1.4379 (0.6276, 3.2944) /0.391	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
Female	5/ 63 (8%)	3/ 64 (5%)	1.7529 (0.4007, 7.6680) /0.456	3.2490 (-5.1990, 11.6970) /0.451	1.6931 (0.4224, 6.7871) /0.457	0.442
Male	8/220 (4%)	9/219 (4%)	0.8805 (0.3334, 2.3257) /0.797	-0.4732 (-4.0831, 3.1366) /0.797	0.8848 (0.3478, 2.2512) /0.797	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.153
Male	13/220 (6%)	9/219 (4%)	1.4654 (0.6131, 3.5023) /0.390	1.7995 (-2.2773, 5.8763) /0.387	1.4379 (0.6276, 3.2944) /0.391	
Bronchitis Female	1/ 63 (2%)	4/ 64 (6%)	0.2419 (0.0263, 2.2273) /0.210	-4.6627 (-11.3481, 2.0227) /0.172	0.2540 (0.0292, 2.2100) /0.214	0.070
Male	11/220 (5%)	6/219 (3%)	1.8684 (0.6786, 5.1446) /0.226	2.2603 (-1.3409, 5.8614) /0.219	1.8250 (0.6870, 4.8479) /0.227	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.255
Male	9/220 (4%)	7/219 (3%)	1.2918 (0.4724, 3.5325) /0.618	0.8946 (-2.6095, 4.3986) /0.617	1.2799 (0.4852, 3.3757) /0.618	
Syphilis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	12/220 (5%)	6/219 (3%)	2.0481 (0.7546, 5.5585) /0.159	2.7148 (-0.9837, 6.4133) /0.150	1.9909 (0.7608, 5.2098) /0.161	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.240
Male	9/220 (4%)	4/219 (2%)	2.2927 (0.6954, 7.5588) /0.173	2.2644 (-0.8973, 5.4261) /0.160	2.2398 (0.7001, 7.1650) /0.174	
Folliculitis Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.689
Male	6/220 (3%)	5/219 (2%)	1.2000 (0.3608, 3.9915) /0.766	0.4442 (-2.4791, 3.3675) /0.766	1.1945 (0.3700, 3.8564) /0.766	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	8/220 (4%)	6/219 (3%)	1.3396 (0.4570, 3.9268) /0.594	0.8966 (-2.3886, 4.1819) /0.593	1.3273 (0.4683, 3.7620) /0.594	
Tonsillitis						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.743
Male	6/220 (3%)	4/219 (2%)	1.5070 (0.4193, 5.4160) /0.530	0.9008 (-1.8880, 3.6896) /0.527	1.4932 (0.4273, 5.2182) /0.530	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.503
Male	4/220 (2%)	5/219 (2%)	0.7926 (0.2100, 2.9917) /0.732	-0.4649 (-3.1164, 2.1866) /0.731	0.7964 (0.2167, 2.9262) /0.732	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
Female	2/ 63 (3%)	6/ 64 (9%)	0.3169 (0.0615, 1.6342) /0.170	-6.2004 (-14.5514, 2.1506) /0.146	0.3386 (0.0710, 1.6147) /0.174	0.172
Male	0/220	4/219 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.091
Male	4/220 (2%)	5/219 (2%)	0.7926 (0.2100, 2.9917) /0.732	-0.4649 (-3.1164, 2.1866) /0.731	0.7964 (0.2167, 2.9262) /0.732	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.508
Male	6/220 (3%)	2/219 (<1%)	3.0421 (0.6072, 15.2402) /0.176	1.8140 (-0.6799, 4.3079) /0.154	2.9864 (0.6094, 14.6346) /0.177	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
Female	0/ 63	3/ 64 (5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	0.103
Male	3/220 (1%)	4/219 (2%)	0.7431 (0.1644, 3.3597) /0.700	-0.4628 (-2.8068, 1.8811) /0.699	0.7466 (0.1691, 3.2969) /0.700	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
Female	0/ 63	3/ 64 (5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	0.005
Male	6/220 (3%)	1/219 (<1%)	6.1121 (0.7297, 51.1963) /0.095	2.2707 (-0.0595, 4.6008) /0.056	5.9727 (0.7250, 49.2014) /0.097	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.613
Male	7/220 (3%)	1/219 (<1%)	7.1643 (0.8740, 58.7267) /0.067	2.7252 (0.2400, 5.2104) /0.032	6.9682 (0.8645, 56.1638) /0.068	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.343
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Anal chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	3/219 (1%)	1.6744 (0.3952, 7.0938) /0.484	0.9029 (-1.5968, 3.4025) /0.479	1.6591 (0.4014, 6.8575) /0.484	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.838
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.218
Male	4/220 (2%)	3/219 (1%)	1.3333 (0.2949, 6.0283) /0.709	0.4483 (-1.8941, 2.7908) /0.708	1.3273 (0.3006, 5.8611) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.167
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	
Hordeolum						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	2/219 (<1%)	2.5233 (0.4843, 13.1469) /0.272	1.3595 (-0.9784, 3.6973) /0.254	2.4886 (0.4880, 12.6905) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
Female	3/ 63 (5%)	1/ 64 (2%)	3.1500 (0.3188, 31.1253) /0.326	3.1994 (-2.8739, 9.2727) /0.302	3.0476 (0.3257, 28.5210) /0.329	0.255
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Proctitis gonococcal						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	4/219 (2%)	0.7431 (0.1644, 3.3597) /0.700	-0.4628 (-2.8068, 1.8811) /0.699	0.7466 (0.1691, 3.2969) /0.700	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	3/219 (1%)	1.3333 (0.2949, 6.0283) /0.709	0.4483 (-1.8941, 2.7908) /0.708	1.3273 (0.3006, 5.8611) /0.709	
Urethritis gonococcal Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	3/219 (1%)	1.3333 (0.2949, 6.0283) /0.709	0.4483 (-1.8941, 2.7908) /0.708	1.3273 (0.3006, 5.8611) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis Female	3/ 63 (5%)	1/ 64 (2%)	3.1500 (0.3188, 31.1253) /0.326	3.1994 (-2.8739, 9.2727) /0.302	3.0476 (0.3257, 28.5210) /0.329	0.535
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.991
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotonsillitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	
Cellulitis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.025
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Genital herpes simplex						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	3/ 63 (5%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.132
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	3/219 (1%)	0.6606 (0.1093, 3.9923) /0.651	-0.4608 (-2.4464, 1.5249) /0.649	0.6636 (0.1120, 3.9329) /0.652	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.700
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.405
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Secondary syphilis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.992
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	3/219 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tracheobronchitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Epididymitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Proctitis chlamydial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinea pedis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Viral pharyngitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Vulvovaginal candidiasis						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	>0.999
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Acute hepatitis B						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Balanitis candida						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Candida infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic tonsillitis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	
Mycoplasma infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Orchitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Otitis media						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin infection Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tinea infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Urethritis chlamydial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abscess limb						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Angular cheilitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anorectal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vulvovaginitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Bronchitis pneumococcal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cat scratch disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Conjunctivitis bacterial						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dacryocystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Erysipelas						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Fungal infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis shigella						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastrointestinal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Genital infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genitourinary tract gonococcal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gingivitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Helicobacter gastritis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Herpes virus infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Infectious colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Lice infestation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranuloma venereum						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Malaria						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Mycoplasma genitalium infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oophoritis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Paronychia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pharyngeal chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post procedural infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pyelonephritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis chronic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Respiratory tract infection bacterial						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Sexually transmitted disease						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin candida						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Staphylococcal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidi asis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tinea cruris						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Upper respiratory tract infection bacterial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis mycoplasmal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vaginal infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Viral tonsillitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal mycotic infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Vulvovaginitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	50/ 63 (79%)	5/ 64 (8%)	45.3846 (15.1366, 136.0781) /<.001	71.5526 (59.5906, 83.5145) /<.001	10.1587 (4.3379, 23.7905) /<.001	0.826
Male	193/220 (88%)	21/219 (10%)	67.3967 (36.8498, 123.2655) /<.001	78.1382 (72.3067, 83.9698) /<.001	9.1487 (6.0735, 13.7809) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	39/ 63 (62%)	0/ 64	>999 (>999, >999) /NC	61.3243 (34.0177, 88.6308) /<.001	NC	NC
Male	188/220 (85%)	0/219	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	10/ 63 (16%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	34/220 (15%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
Female	19/ 63 (30%)	0/ 64	>999 (>999, >999) /NC	31.1249 (4.0472, 58.2026) /0.024	>999 (>999, >999) /NC	NC
Male	19/220 (9%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.398
Male	20/220 (9%)	4/219 (2%)	5.3750 (1.8060, 15.9971) /0.003	7.2644 (3.0720, 11.4568) /<.001	4.9773 (1.7294, 14.3245) /0.003	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
Female	6/ 63 (10%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	17/220 (8%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
Female	8/ 63 (13%)	0/ 64	>999 (>999, >999) /NC	14.5108 (-11.6545, 40.6760) /0.277	>999 (>999, >999) /NC	NC
Male	8/220 (4%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.252
Male	7/220 (3%)	7/219 (3%)	0.9953 (0.3432, 2.8865) /0.993	-0.0145 (-3.3019, 3.2728) /0.993	0.9955 (0.3551, 2.7906) /0.993	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.888
Male	6/220 (3%)	5/219 (2%)	1.2000 (0.3608, 3.9915) /0.766	0.4442 (-2.4791, 3.3675) /0.766	1.1945 (0.3700, 3.8564) /0.766	
Asthenia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	12/220 (5%)	1/219 (<1%)	12.5769 (1.6210, 97.5812) /0.015	4.9979 (1.8671, 8.1288) /0.002	11.9454 (1.5667, 91.0808) /0.017	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
Female	7/ 63 (11%)	0/ 64	>999 (>999, >999) /NC	12.9993 (-13.0566, 39.0552) /0.328	>999 (>999, >999) /NC	NC
Male	6/220 (3%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
Female	3/ 63 (5%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Malaise						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.072
Male	6/220 (3%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.190
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Nodule						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Feeling hot						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haemorrhage						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catheter site erythema						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Chest discomfort						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site anaesthesia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cyst						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site granuloma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Injection site necrosis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site scar						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Non-cardiac chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Swelling						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Systemic inflammatory response syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Temperature regulation disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site bruise						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	13/ 63 (21%)	16/ 64 (25%)	0.7800 (0.3394, 1.7926) /0.558	-4.3651 (-18.9391, 10.2089) /0.557	0.8254 (0.4335, 1.5714) /0.559	0.065
Male	94/220 (43%)	59/219 (27%)	2.0231 (1.3553, 3.0199) /<.001	15.7866 (6.9972, 24.5761) /<.001	1.5860 (1.2151, 2.0701) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	4/ 63 (6%)	2/ 64 (3%)	2.1017 (0.3710, 11.9073) /0.401	3.2242 (-4.1533, 10.6017) /0.392	2.0317 (0.3858, 10.7000) /0.403	0.552
Male	28/220 (13%)	23/219 (11%)	1.2428 (0.6914, 2.2338) /0.468	2.2250 (-3.7652, 8.2152) /0.467	1.2119 (0.7213, 2.0361) /0.468	
Nausea						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.764
Male	14/220 (6%)	10/219 (5%)	1.4204 (0.6169, 3.2705) /0.410	1.7974 (-2.4509, 6.0458) /0.407	1.3936 (0.6327, 3.0696) /0.410	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.782
Male	10/220 (5%)	7/219 (3%)	1.4422 (0.5388, 3.8601) /0.466	1.3491 (-2.2569, 4.9552) /0.463	1.4221 (0.5513, 3.6682) /0.466	
Haemorrhoids						
Female	3/ 63 (5%)	1/ 64 (2%)	3.1500 (0.3188, 31.1253) /0.326	3.1994 (-2.8739, 9.2727) /0.302	3.0476 (0.3257, 28.5210) /0.329	0.593
Male	13/220 (6%)	2/219 (<1%)	6.8140 (1.5192, 30.5636) /0.012	4.9958 (1.6350, 8.3567) /0.004	6.4705 (1.4775, 28.3363) /0.013	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache	Female	0/ 63	1/ 64 (2%) <0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.171
	Male	7/220 (3%)	4/219 (2%) 1.7664 (0.5096, 6.1224) /0.370	1.3553 (-1.5643, 4.2750) /0.363	1.7420 (0.5173, 5.8662) /0.370	
Vomiting	Female	2/ 63 (3%)	0/ 64 >999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.226
	Male	6/220 (3%)	3/219 (1%) 2.0187 (0.4984, 8.1759) /0.325	1.3574 (-1.2888, 4.0036) /0.315	1.9909 (0.5043, 7.8602) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.196
Male	5/220 (2%)	3/219 (1%)	1.6744 (0.3952, 7.0938) /0.484	0.9029 (-1.5968, 3.4025) /0.479	1.6591 (0.4014, 6.8575) /0.484	
Dyspepsia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.378
Male	6/220 (3%)	3/219 (1%)	2.0187 (0.4984, 8.1759) /0.325	1.3574 (-1.2888, 4.0036) /0.315	1.9909 (0.5043, 7.8602) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	7/220 (3%)	2/219 (<1%)	3.5657 (0.7324, 17.3599) /0.115	2.2686 (-0.3708, 4.9080) /0.092	3.4841 (0.7319, 16.5850) /0.117	
Abdominal pain upper						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.085
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.167
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anogenital dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.105
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Dental caries						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.105
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.209
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.278
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.412
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Abdominal pain lower						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.308
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Haemorrhoidal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal inflammation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea haemorrhagic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dry mouth						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Gastroduodenitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival bleeding						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Inguinal hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rectal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Stomatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Aerophagia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal pruritus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Aphthous ulcer						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Barrett's oesophagus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bile acid malabsorption						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bowel movement irregularity						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis microscopic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysbacteriosis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enteritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enterocolitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epigastric discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastrointestinal sounds abnormal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gingival swelling						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematochezi ^a						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Irritable bowel syndrome						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Large intestine perforation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Leukoplakia oral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oesophageal polyp						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Palatal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Paraesthesia oral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rectal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue eruption						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Tooth development disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	14/ 63 (22%)	14/ 64 (22%)	1.0204 (0.4409, 2.3614) /0.962	0.3472 (-14.0739, 14.7683) /0.962	1.0159 (0.5282, 1.9538) /0.962	0.214
Male	50/220 (23%)	30/219 (14%)	1.8529 (1.1263, 3.0483) /0.015	9.0286 (1.8591, 16.1982) /0.014	1.6591 (1.0987, 2.5053) /0.016	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
Female	5/ 63 (8%)	5/ 64 (8%)	1.0172 (0.2796, 3.7009) /0.979	0.1240 (-9.2452, 9.4932) /0.979	1.0159 (0.3091, 3.3385) /0.979	0.320
Male	17/220 (8%)	8/219 (4%)	2.2087 (0.9327, 5.2308) /0.072	4.0743 (-0.2412, 8.3898) /0.064	2.1153 (0.9324, 4.7992) /0.073	
Myalgia						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.248
Male	12/220 (5%)	5/219 (2%)	2.4692 (0.8550, 7.1313) /0.095	3.1714 (-0.4227, 6.7656) /0.084	2.3891 (0.8560, 6.6677) /0.096	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
Female	2/ 63 (3%)	3/ 64 (5%)	0.6667 (0.1076, 4.1313) /0.663	-1.5129 (-8.2627, 5.2369) /0.660	0.6773 (0.1171, 3.9171) /0.663	0.379
Male	7/220 (3%)	4/219 (2%)	1.7664 (0.5096, 6.1224) /0.370	1.3553 (-1.5643, 4.2750) /0.363	1.7420 (0.5173, 5.8662) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.051
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.144
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.343
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pain in extremity						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck pain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	3/219 (1%)	0.6606 (0.1093, 3.9923) /0.651	-0.4608 (-2.4464, 1.5249) /0.649	0.6636 (0.1120, 3.9329) /0.652	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondro sis						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.278
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tendonitis						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Plantar fasciitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Spinal disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Arthritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Groin pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Joint swelling						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Osteoporosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Soft tissue mass						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tendon pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	13/ 63 (21%)	11/ 64 (17%)	1.2527 (0.5139, 3.0539) /0.620	3.4474 (-10.1648, 17.0596) /0.620	1.2006 (0.5822, 2.4756) /0.621	0.140
Male	51/220 (23%)	22/219 (10%)	2.7023 (1.5739, 4.6395) /<.001	13.1362 (6.2845, 19.9878) /<.001	2.3076 (1.4515, 3.6687) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
Female	6/ 63 (10%)	5/ 64 (8%)	1.2421 (0.3589, 4.2982) /0.732	1.7113 (-8.0749, 11.4976) /0.732	1.2190 (0.3919, 3.7915) /0.732	0.424
Male	33/220 (15%)	16/219 (7%)	2.2390 (1.1933, 4.2008) /0.012	7.6941 (1.8509, 13.5372) /0.010	2.0531 (1.1646, 3.6196) /0.013	
Dizziness						
Female	5/ 63 (8%)	2/ 64 (3%)	2.6724 (0.4988, 14.3169) /0.251	4.8115 (-3.1083, 12.7313) /0.234	2.5397 (0.5115, 12.6106) /0.254	0.286
Male	10/220 (5%)	1/219 (<1%)	10.3810 (1.3174, 81.8033) /0.026	4.0888 (1.1951, 6.9825) /0.006	9.9545 (1.2852, 77.1015) /0.028	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.190
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Paraesthesia Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Amnesia Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Dysarthria						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Neuropathy peripheral						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Poor quality sleep						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Presyncope						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Anosmia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cervical neuritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nerve compression						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Post herpetic neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Tension headache						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tremor						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Trigeminal neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Visual field defect						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	5/ 63 (8%)	5/ 64 (8%)	1.0172 (0.2796, 3.7009) /0.979	0.1240 (-9.2452, 9.4932) /0.979	1.0159 (0.3091, 3.3385) /0.979	0.517
Male	42/220 (19%)	27/219 (12%)	1.6779 (0.9929, 2.8356) /0.053	6.7621 (-0.0151, 13.5394) /0.051	1.5485 (0.9915, 2.4183) /0.055	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.115
Male	6/220 (3%)	6/219 (3%)	0.9953 (0.3160, 3.1352) /0.994	-0.0125 (-3.0631, 3.0382) /0.994	0.9955 (0.3261, 3.0388) /0.994	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.248
Male	6/220 (3%)	6/219 (3%)	0.9953 (0.3160, 3.1352) /0.994	-0.0125 (-3.0631, 3.0382) /0.994	0.9955 (0.3261, 3.0388) /0.994	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Seborrhoeic dermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Erythema						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosi s						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Skin lesion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dermatitis atopic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dyshidrotic eczema						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Intertrigo						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Papule						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pruritus generalised						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash pruritic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash vesicular						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Urticaria						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Blood blister Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dermatitis allergic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ephelides						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Granuloma annulare						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value (RR)

Lipodystrophy acquired						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nail pigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile ulceration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pityriasis alba						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Psoriasis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Rash generalised						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash maculo-papular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash morbilliform						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash papular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin erosion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin hyperpigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypopigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin induration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Skin reaction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Xeroderma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	8/ 63 (13%)	5/ 64 (8%)	1.7164 (0.5294, 5.5645) /0.368	4.8859 (-5.6415, 15.4133) /0.363	1.6254 (0.5621, 4.7001) /0.370	0.605
Male	35/220 (16%)	29/219 (13%)	1.2395 (0.7280, 2.1104) /0.429	2.6671 (-3.9293, 9.2634) /0.428	1.2014 (0.7621, 1.8940) /0.429	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	2/ 63 (3%)	3/ 64 (5%)	0.6667 (0.1076, 4.1313) /0.663	-1.5129 (-8.2627, 5.2369) /0.660	0.6773 (0.1171, 3.9171) /0.663	0.791
Male	8/220 (4%)	9/219 (4%)	0.8805 (0.3334, 2.3257) /0.797	-0.4732 (-4.0831, 3.1366) /0.797	0.8848 (0.3478, 2.2512) /0.797	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
Female	4/ 63 (6%)	0/ 64	>999 (>999, >999) /NC	8.4601 (-17.2551, 34.1754) /0.519	>999 (>999, >999) /NC	0.094
Male	8/220 (4%)	4/219 (2%)	2.0283 (0.6017, 6.8368) /0.254	1.8099 (-1.2338, 4.8535) /0.244	1.9909 (0.6084, 6.5153) /0.255	
Rhinitis allergic						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	10/220 (5%)	1/219 (<1%)	10.3810 (1.3174, 81.8033) /0.026	4.0888 (1.1951, 6.9825) /0.006	9.9545 (1.2852, 77.1015) /0.028	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	
Nasal congestion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	5/219 (2%)	0.3927 (0.0754, 2.0459) /0.267	-1.3740 (-3.7163, 0.9683) /0.250	0.3982 (0.0781, 2.0305) /0.268	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	4/219 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Epistaxis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Respiratory disorder						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchial obstruction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis chronic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchospasm						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal dryness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal obstruction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal turbinate hypertrophy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Nasal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reflux laryngitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Throat irritation						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillar hypertrophy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Upper respiratory tract inflammation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
Female	5/ 63 (8%)	6/ 64 (9%)	0.8333 (0.2408, 2.8836) /0.773	-1.4385 (-11.2134, 8.3364) /0.773	0.8466 (0.2722, 2.6330) /0.774	0.982
Male	26/220 (12%)	31/219 (14%)	0.8128 (0.4650, 1.4207) /0.467	-2.3371 (-8.6229, 3.9488) /0.466	0.8349 (0.5133, 1.3580) /0.467	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.386
Male	3/220 (1%)	6/219 (3%)	0.4908 (0.1212, 1.9877) /0.319	-1.3761 (-4.0261, 1.2739) /0.309	0.4977 (0.1261, 1.9650) /0.319	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.584
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	
Laceration						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	2/219 (<1%)	2.5233 (0.4843, 13.1469) /0.272	1.3595 (-0.9784, 3.6973) /0.254	2.4886 (0.4880, 12.6905) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.190
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Thermal burn						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ankle fracture						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Fall						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Limb injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Multiple injuries						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Penis injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin abrasion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bone contusion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Craniocerebral injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Epicondylitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure via inhalation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Foot fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hand fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Joint injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Penile contusion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post lumbar puncture syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Post procedural haemorrhage						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Road traffic accident						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Soft tissue injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal column injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sunburn						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tibia fracture						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Traumatic haematoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethral injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	10/ 63 (16%)	11/ 64 (17%)	0.9091 (0.3561, 2.3207) /0.842	-1.3145 (-14.2318, 11.6028) /0.842	0.9235 (0.4223, 2.0198) /0.842	0.136
Male	31/220 (14%)	16/219 (7%)	2.0810 (1.1028, 3.9270) /0.024	6.7850 (1.0390, 12.5310) /0.021	1.9287 (1.0868, 3.4227) /0.025	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.165
Male	9/220 (4%)	5/219 (2%)	1.8256 (0.6019, 5.5374) /0.288	1.8078 (-1.4731, 5.0887) /0.280	1.7918 (0.6103, 5.2610) /0.289	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	8/220 (4%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.063
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.664
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.051
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Blood glucose abnormal						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Aortic bruit						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood creatinine increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood folate decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Blood triglycerides increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Electrocardiogram QT prolonged						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haemoglobin decreased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heart rate increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatic enzyme increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mycoplasma test positive						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Platelet count decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Protein urine present						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Total lung capacity decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Treponema test positive						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Weight increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	7/ 63 (11%)	4/ 64 (6%)	1.8750 (0.5206, 6.7526) /0.336	4.8611 (-4.9058, 14.6280) /0.329	1.7778 (0.5473, 5.7751) /0.338	0.664
Male	31/220 (14%)	23/219 (11%)	1.3977 (0.7864, 2.4845) /0.254	3.5886 (-2.5453, 9.7225) /0.252	1.3417 (0.8090, 2.2252) /0.255	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.197
Male	11/220 (5%)	6/219 (3%)	1.8684 (0.6786, 5.1446) /0.226	2.2603 (-1.3409, 5.8614) /0.219	1.8250 (0.6870, 4.8479) /0.227	
Insomnia Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.669
Male	6/220 (3%)	3/219 (1%)	2.0187 (0.4984, 8.1759) /0.325	1.3574 (-1.2888, 4.0036) /0.315	1.9909 (0.5043, 7.8602) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.119
Male	4/220 (2%)	4/219 (2%)	0.9954 (0.2458, 4.0312) /0.995	-0.0083 (-2.5108, 2.4942) /0.995	0.9955 (0.2521, 3.9301) /0.995	
Abnormal dreams						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.278
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Depressed mood						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Adjustment disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nervousness						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Stress						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal ideation						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Acute stress disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Affective disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Drug abuse						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Major depression						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paranoia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Suicide attempt						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	7/ 63 (11%)	3/ 64 (5%)	2.5417 (0.6266, 10.3100) /0.192	6.4236 (-2.9059, 15.7531) /0.177	2.3704 (0.6415, 8.7587) /0.196	0.390
Male	26/220 (12%)	20/219 (9%)	1.3335 (0.7205, 2.4679) /0.359	2.6858 (-3.0373, 8.4088) /0.358	1.2941 (0.7451, 2.2477) /0.360	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	5/ 63 (8%)	1/ 64 (2%)	5.4310 (0.6161, 47.8744) /0.128	6.3740 (-0.9598, 13.7078) /0.088	5.0794 (0.6105, 42.2605) /0.133	0.235
Male	18/220 (8%)	12/219 (5%)	1.5371 (0.7219, 3.2728) /0.265	2.7024 (-2.0096, 7.4143) /0.261	1.4932 (0.7370, 3.0252) /0.266	
Hypophosphat aemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	4/219 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypovitaminosis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Hypercholesterolaemia						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hyperlipasae mia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertriglyceridaemia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Diabetes mellitus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Glucose tolerance impaired						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gout						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypocalcaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Hypomagnesaemia						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Iron deficiency						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	4/ 63 (6%)	2/ 64 (3%)	2.1017 (0.3710, 11.9073) /0.401	3.2242 (-4.1533, 10.6017) /0.392	2.0317 (0.3858, 10.7000) /0.403	0.497
Male	19/220 (9%)	17/219 (8%)	1.1232 (0.5674, 2.2234) /0.739	0.8738 (-4.2582, 6.0058) /0.739	1.1126 (0.5943, 2.0827) /0.739	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	12/220 (5%)	6/219 (3%)	2.0481 (0.7546, 5.5585) /0.159	2.7148 (-0.9837, 6.4133) /0.150	1.9909 (0.7608, 5.2098) /0.161	
Skin papilloma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Lipoma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oral papilloma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Uterine leiomyoma						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	
Adenocarcinoma of colon						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal neoplasm						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Benign spleen tumour						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Dysplastic naevus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Kidney angiomyolipoma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasm skin						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oral fibroma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin cancer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	7/ 63 (11%)	9/ 64 (14%)	0.7639 (0.2659, 2.1949) /0.617	-2.9514 (-14.4735, 8.5708) /0.616	0.7901 (0.3135, 1.9915) /0.617	0.414
Male	12/220 (5%)	9/219 (4%)	1.3462 (0.5554, 3.2626) /0.510	1.3450 (-2.6447, 5.3346) /0.509	1.3273 (0.5708, 3.0861) /0.511	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.683
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Erectile dysfunction						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Prostatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	
Genital lesion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Breast pain						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysfunctional uterine bleeding						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe						
^a Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Menopausal symptoms						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Ovarian cyst						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Polymenorrhoea						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Testicular pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Vaginal dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal haemorrhage						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Vaginal ulceration						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vulvar dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	5/ 63 (8%)	4/ 64 (6%)	1.2931 (0.3308, 5.0554) /0.712	1.6865 (-7.2422, 10.6152) /0.711	1.2698 (0.3573, 4.5124) /0.712	0.889
Male	10/220 (5%)	7/219 (3%)	1.4422 (0.5388, 3.8601) /0.466	1.3491 (-2.2569, 4.9552) /0.463	1.4221 (0.5513, 3.6682) /0.466	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
Female	3/ 63 (5%)	3/ 64 (5%)	1.0167 (0.1973, 5.2385) /0.984	0.0744 (-7.3060, 7.4548) /0.984	1.0159 (0.2130, 4.8442) /0.984	0.426
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.102
Male	1/220 (<1%)	4/219 (2%)	0.2454 (0.0272, 2.2136) /0.211	-1.3719 (-3.3557, 0.6118) /0.175	0.2489 (0.0280, 2.2088) /0.212	
Eosinophilia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypochromic anaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lymphadenitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Normocytic anaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Splenomegaly						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	5/ 63 (8%)	3/ 64 (5%)	1.7529 (0.4007, 7.6680) /0.456	3.2490 (-5.1990, 11.6970) /0.451	1.6931 (0.4224, 6.7871) /0.457	0.783
Male	8/220 (4%)	6/219 (3%)	1.3396 (0.4570, 3.9268) /0.594	0.8966 (-2.3886, 4.1819) /0.593	1.3273 (0.4683, 3.7620) /0.594	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.195
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	
Proteinuria Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.049
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Renal failure						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Calculus urinary						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Glomerulonephritis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition urgency						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nephrolithiasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Nephropathy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pollakiuria						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral caruncle						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Urethral discharge						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Urinary incontinence						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.771
Male	11/220 (5%)	7/219 (3%)	1.5940 (0.6063, 4.1910) /0.345	1.8037 (-1.9006, 5.5079) /0.340	1.5643 (0.6178, 3.9606) /0.345	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Asthenopia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Blepharospasm						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Chalazion Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chorioretinal disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Conjunctivitis allergic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic retinopathy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dry eye						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye irritation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye pruritus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glare						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Glaucoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lacrimation increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Meibomian gland dysfunction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Uveitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.073
Male	9/220 (4%)	3/219 (1%)	3.0711 (0.8201, 11.5002) /0.096	2.7210 (-0.3156, 5.7576) /0.079	2.9864 (0.8194, 10.8834) /0.097	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	
Ear pain						
Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.136
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.051
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vertigo positional Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Noninfective myringitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	3/ 63 (5%)	3/ 64 (5%)	1.0167 (0.1973, 5.2385) /0.984	0.0744 (-7.3060, 7.4548) /0.984	1.0159 (0.2130, 4.8442) /0.984	0.120
Male	7/220 (3%)	1/219 (<1%)	7.1643 (0.8740, 58.7267) /0.067	2.7252 (0.2400, 5.2104) /0.032	6.9682 (0.8645, 56.1638) /0.068	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.051
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Circulatory collapse						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Hyperaemia Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Intermittent claudication						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral artery thrombosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Peripheral ischaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral venous disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Thrombophlebitis superficial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value (RR)
Immune system disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	10/220 (5%)	3/219 (1%)	3.4285 (0.9306, 12.6322) /0.064	3.1756 (0.0219, 6.3293) /0.048	3.3182 (0.9257, 11.8934) /0.066	
Seasonal allergy						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	6/220 (3%)	1/219 (<1%)	6.1121 (0.7297, 51.1963) /0.095	2.2707 (-0.0595, 4.6008) /0.056	5.9727 (0.7250, 49.2014) /0.097	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Food allergy						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mite allergy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	6/220 (3%)	1/219 (<1%)	6.1121 (0.7297, 51.1963) /0.095	2.2707 (-0.0595, 4.6008) /0.056	5.9727 (0.7250, 49.2014) /0.097	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperbilirubinaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bile duct stone						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cholelithiasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hepatic steatosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis toxic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hydrocholecystis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-alcoholic steatohepatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Atrioventricular block first degree						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Goitre						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypothyroidism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Keratosis follicular						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth extraction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	205/216 (95%)	155/201 (77%)	5.5308 (2.7738, 11.0281) /<.001	17.7930 (11.2873, 24.2987) /<.001	1.2307 (1.1345, 1.3351) /<.001	0.095
Non-White	62/ 67 (93%)	68/ 80 (85%)	2.1882 (0.7294, 6.5645) /0.162	7.5373 (-2.5035, 17.5781) /0.141	1.0887 (0.9709, 1.2207) /0.146	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	148/216 (69%)	127/201 (63%)	1.2682 (0.8452, 1.9028) /0.251	5.3344 (-3.7661, 14.4350) /0.251	1.0844 (0.9437, 1.2461) /0.253	0.262
Non-White	48/ 67 (72%)	45/ 80 (56%)	1.9649 (0.9847, 3.9210) /0.055	15.3918 (0.0734, 30.7102) /0.049	1.2736 (0.9968, 1.6273) /0.053	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	46/216 (21%)	37/201 (18%)	1.1994 (0.7399, 1.9442) /0.461	2.8883 (-4.7611, 10.5377) /0.459	1.1569 (0.7850, 1.7051) /0.461	0.887
Non-White	10/ 67 (15%)	11/ 80 (14%)	1.1005 (0.4362, 2.7765) /0.839	1.1754 (-10.2154, 12.5661) /0.840	1.0855 (0.4914, 2.3977) /0.839	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	25/216 (12%)	16/201 (8%)	1.5134 (0.7828, 2.9260) /0.218	3.6139 (-2.0610, 9.2887) /0.212	1.4540 (0.8001, 2.6424) /0.219	0.951
Non-White	13/ 67 (19%)	11/ 80 (14%)	1.5101 (0.6274, 3.6348) /0.358	5.6530 (-6.4552, 17.7612) /0.360	1.4111 (0.6770, 2.9411) /0.358	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	20/216 (9%)	14/201 (7%)	1.3630 (0.6689, 2.7772) /0.394	2.2941 (-2.9334, 7.5216) /0.390	1.3294 (0.6902, 2.5603) /0.395	0.665
Non-White	5/ 67 (7%)	6/ 80 (8%)	0.9946 (0.2896, 3.4160) /0.993	-0.0373 (-8.5759, 8.5012) /0.993	0.9950 (0.3177, 3.1161) /0.993	
Gastroenteritis						
White	13/216 (6%)	9/201 (4%)	1.3662 (0.5709, 3.2691) /0.483	1.5409 (-2.7292, 5.8110) /0.479	1.3441 (0.5873, 3.0761) /0.484	0.912
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	13/216 (6%)	12/201 (6%)	1.0086 (0.4490, 2.2656) /0.983	0.0484 (-4.5110, 4.6078) /0.983	1.0081 (0.4711, 2.1572) /0.983	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pharyngitis						
White	11/216 (5%)	8/201 (4%)	1.2945 (0.5099, 3.2865) /0.587	1.1125 (-2.8749, 5.0999) /0.584	1.2795 (0.5253, 3.1165) /0.587	0.232
Non-White	4/ 67 (6%)	1/ 80 (1%)	5.0159 (0.5469, 46.0064) /0.154	4.7201 (-1.4535, 10.8938) /0.134	4.7761 (0.5469, 41.7109) /0.157	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
White	11/216 (5%)	8/201 (4%)	1.2945 (0.5099, 3.2865) /0.587	1.1125 (-2.8749, 5.0999) /0.584	1.2795 (0.5253, 3.1165) /0.587	0.546
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	
Rhinitis						
White	9/216 (4%)	8/201 (4%)	1.0489 (0.3967, 2.7735) /0.923	0.1866 (-3.6089, 3.9820) /0.923	1.0469 (0.4119, 2.6608) /0.923	0.660
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Syphilis						
White	8/216 (4%)	6/201 (3%)	1.2500 (0.4260, 3.6675) /0.685	0.7186 (-2.7278, 4.1650) /0.683	1.2407 (0.4381, 3.5136) /0.685	0.032
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oral herpes						
White	8/216 (4%)	4/201 (2%)	1.8942 (0.5615, 6.3901) /0.303	1.7137 (-1.4598, 4.8871) /0.290	1.8611 (0.5692, 6.0856) /0.304	0.108
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
White	6/216 (3%)	4/201 (2%)	1.4071 (0.3912, 5.0610) /0.601	0.7877 (-2.1330, 3.7084) /0.597	1.3958 (0.3997, 4.8743) /0.601	0.894
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	
Gonorrhoea						
White	4/216 (2%)	6/201 (3%)	0.6132 (0.1705, 2.2055) /0.454	-1.1332 (-4.0942, 1.8277) /0.453	0.6204 (0.1777, 2.1664) /0.454	0.010
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tonsillitis						
White	8/216 (4%)	5/201 (2%)	1.5077 (0.4850, 4.6872) /0.478	1.2161 (-2.0973, 4.5296) /0.472	1.4889 (0.4953, 4.4761) /0.478	0.215
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Respiratory tract infection						
White	5/216 (2%)	8/201 (4%)	0.5717 (0.1839, 1.7773) /0.334	-1.6653 (-5.0306, 1.7000) /0.332	0.5816 (0.1935, 1.7485) /0.335	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
White	0/216	8/201 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.014
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
White	5/216 (2%)	4/201 (2%)	1.1671 (0.3090, 4.4085) /0.820	0.3248 (-2.4590, 3.1085) /0.819	1.1632 (0.3168, 4.2710) /0.820	0.987
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Conjunctivitis						
White	7/216 (3%)	3/201 (1%)	2.2105 (0.5637, 8.6679) /0.255	1.7482 (-1.1478, 4.6442) /0.237	2.1713 (0.5692, 8.2823) /0.256	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
White	2/216 (<1%)	4/201 (2%)	0.4603 (0.0834, 2.5407) /0.373	-1.0641 (-3.3791, 1.2509) /0.368	0.4653 (0.0862, 2.5127) /0.374	0.913
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	0.256
Non-White	2/ 67 (3%)	3/ 80 (4%)	0.7897 (0.1280, 4.8712) /0.799	-0.7649 (-6.5904, 5.0605) /0.797	0.7960 (0.1370, 4.6245) /0.799	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
White	6/216 (3%)	1/201 (<1%)	5.7142 (0.6819, 47.8846) /0.108	2.2803 (-0.1174, 4.6780) /0.062	5.5833 (0.6781, 45.9731) /0.110	0.416
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	0.683
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
White	4/216 (2%)	3/201 (1%)	1.2453 (0.2753, 5.6338) /0.776	0.3593 (-2.0988, 2.8174) /0.774	1.2407 (0.2812, 5.4755) /0.776	0.267
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.101
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
White	4/216 (2%)	3/201 (1%)	1.2453 (0.2753, 5.6338) /0.776	0.3593 (-2.0988, 2.8174) /0.774	1.2407 (0.2812, 5.4755) /0.776	0.254
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.224
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hordeolum						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.543
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	0.696
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.224
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.543
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.296
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	0.385
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotons illitis						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Cellulitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.520
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.236
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Genital herpes simplex						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.236
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.611
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.110
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Fungal skin infection						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Subcutaneous abscess						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.157
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Tracheobronchitis						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Epididymitis						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Helicobacter infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Proctitis chlamydial						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
White	0/216	0/201	NC	NC	NC	>0.999
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Vulvovaginal candidiasis						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
White	0/216	0/201	NC	NC	NC	>0.999
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Acute hepatitis B						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Anal abscess						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Balanitis candida						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chronic tonsillitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Mycoplasma infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Onychomycosis						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Otitis externa						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pneumonia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Tinea infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Urethritis chlamydial						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Abscess limb						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Angular cheilitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anorectal infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vulvovaginitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Bronchitis pneumococcal						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cat scratch disease						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Conjunctivitis bacterial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dacryocystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Erysipelas						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Fungal infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis shigella						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gastrointestinal infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genital infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary chlamydia infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genitourinary tract gonococcal infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gingivitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Helicobacter gastritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Herpes virus infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Infectious colitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Lice infestation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranuloma venereum						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Malaria						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Oophoritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Paronychia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pharyngeal chlamydia infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Post procedural infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Pyelonephritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis chronic						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Respiratory tract infection bacterial						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotavirus infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Sexually transmitted disease						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Skin candida						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Staphylococcal abscess						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidi asis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tinea cruris						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Upper respiratory tract infection bacterial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urethritis mycoplasmal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Vaginal infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Viral tonsillitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal mycotic infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Vulvovaginitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	191/216 (88%)	20/201 (10%)	69.1419 (37.1147, 128.8061) /<.001	78.4757 (72.5321, 84.4192) /<.001	8.8868 (5.8468, 13.5075) /<.001	0.732
Non-White	52/ 67 (78%)	6/ 80 (8%)	42.7556 (15.5568, 117.5074) /<.001	70.1119 (58.5821, 81.6418) /<.001	10.3483 (4.7426, 22.5797) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	180/216 (83%)	0/201	>999 (>999, >999) /NC	NC	NC	NC
Non-White	47/ 67 (70%)	0/ 80	>999 (>999, >999) /NC	NC	NC	
Injection site nodule						
White	33/216 (15%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	11/ 67 (16%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
White	37/216 (17%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	16/216 (7%)	4/201 (2%)	3.9400 (1.2943, 11.9934) /0.016	5.4174 (1.4267, 9.4080) /0.008	3.7222 (1.2657, 10.9463) /0.017	0.091
Non-White	6/ 67 (9%)	0/ 80	>999 (>999, >999) /NC	10.9455 (-12.4355, 34.3266) /0.359	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
White	19/216 (9%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
White	14/216 (6%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	5/216 (2%)	6/201 (3%)	0.7701 (0.2313, 2.5638) /0.670	-0.6703 (-3.7616, 2.4210) /0.671	0.7755 (0.2404, 2.5015) /0.670	0.709
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
White	8/216 (4%)	6/201 (3%)	1.2500 (0.4260, 3.6675) /0.685	0.7186 (-2.7278, 4.1650) /0.683	1.2407 (0.4381, 3.5136) /0.685	0.243
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Asthenia						
White	10/216 (5%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.090
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Malaise						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.254
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	6/216 (3%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Discomfort						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nodule						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pain						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chest pain						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haemorrhage						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Catheter site erythema						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chills						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site cyst						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Injection site granuloma						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site scar						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Oedema peripheral						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Swelling						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Systemic inflammatory response syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vessel puncture site bruise						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	81/216 (38%)	46/201 (23%)	2.0217 (1.3163, 3.1053) /0.001	14.6144 (5.9305, 23.2984) /<.001	1.6386 (1.2058, 2.2266) /0.002	0.106
Non-White	26/ 67 (39%)	29/ 80 (36%)	1.1152 (0.5705, 2.1799) /0.750	2.5560 (-13.1641, 18.2760) /0.750	1.0705 (0.7047, 1.6263) /0.749	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	26/216 (12%)	16/201 (8%)	1.5822 (0.8220, 3.0456) /0.170	4.0768 (-1.6532, 9.8068) /0.163	1.5122 (0.8362, 2.7345) /0.171	0.267
Non-White	6/ 67 (9%)	9/ 80 (11%)	0.7760 (0.2614, 2.3037) /0.648	-2.2948 (-12.0257, 7.4361) /0.644	0.7960 (0.2986, 2.1224) /0.648	
Nausea						
White	13/216 (6%)	5/201 (2%)	2.5103 (0.8785, 7.1730) /0.086	3.5310 (-0.3025, 7.3644) /0.071	2.4194 (0.8783, 6.6652) /0.087	0.091
Non-White	3/ 67 (4%)	6/ 80 (8%)	0.5781 (0.1389, 2.4055) /0.451	-3.0224 (-10.6274, 4.5826) /0.436	0.5970 (0.1552, 2.2969) /0.453	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	0.597
Non-White	7/ 67 (10%)	6/ 80 (8%)	1.4389 (0.4591, 4.5096) /0.532	2.9478 (-6.3773, 12.2728) /0.536	1.3930 (0.4919, 3.9451) /0.533	
Haemorrhoids						
White	11/216 (5%)	2/201 (<1%)	5.3390 (1.1686, 24.3919) /0.031	4.0976 (0.8605, 7.3346) /0.013	5.1181 (1.1485, 22.8081) /0.032	0.907
Non-White	5/ 67 (7%)	1/ 80 (1%)	6.3710 (0.7255, 55.9459) /0.095	6.2127 (-0.5343, 12.9597) /0.071	5.9701 (0.7149, 49.8555) /0.099	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Toothache						
White	7/216 (3%)	5/201 (2%)	1.3129 (0.4099, 4.2052) /0.647	0.7532 (-2.4425, 3.9489) /0.644	1.3028 (0.4202, 4.0388) /0.647	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vomiting						
White	7/216 (3%)	1/201 (<1%)	6.6985 (0.8168, 54.9332) /0.076	2.7432 (0.1892, 5.2972) /0.035	6.5139 (0.8085, 52.4784) /0.078	0.112
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.133
Non-White	4/ 67 (6%)	3/ 80 (4%)	1.6296 (0.3516, 7.5525) /0.533	2.2201 (-4.8168, 9.2571) /0.536	1.5920 (0.3692, 6.8644) /0.533	
Dyspepsia						
White	6/216 (3%)	3/201 (1%)	1.8857 (0.4653, 7.6426) /0.374	1.2852 (-1.4739, 4.0444) /0.361	1.8611 (0.4717, 7.3427) /0.375	0.336
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
White	7/216 (3%)	1/201 (<1%)	6.6985 (0.8168, 54.9332) /0.076	2.7432 (0.1892, 5.2972) /0.035	6.5139 (0.8085, 52.4784) /0.078	0.076
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.161
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.543
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.116
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.244
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	0.127
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.066
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Flatulence						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Abdominal distension						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal inflammation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Diarrhoea haemorrhagic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Faeces soft						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroduodenitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gingival bleeding						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lip dry						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Stomatitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aerophagia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal fistula						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Barrett's oesophagus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile acid malabsorption						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bowel movement irregularity						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Colitis microscopic White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysbacteriosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Enteritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterocolitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Epigastric discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal sounds abnormal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Gingival pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival swelling						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Haematochezi a						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Large intestine perforation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lymphoid hyperplasia of intestine						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal polyp						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Oral pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Palatal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pancreatitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Paraesthesia oral						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rectal discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal fissure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tongue eruption						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth development disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Umbilical hernia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	48/216 (22%)	33/201 (16%)	1.4545 (0.8892, 2.3793) /0.136	5.8043 (-1.7432, 13.3518) /0.132	1.3535 (0.9078, 2.0181) /0.137	0.540
Non-White	16/ 67 (24%)	11/ 80 (14%)	1.9679 (0.8422, 4.5983) /0.118	10.1306 (-2.5646, 22.8258) /0.118	1.7368 (0.8662, 3.4823) /0.120	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	16/216 (7%)	10/201 (5%)	1.5280 (0.6766, 3.4506) /0.308	2.4323 (-2.1757, 7.0402) /0.301	1.4889 (0.6919, 3.2040) /0.309	0.545
Non-White	6/ 67 (9%)	3/ 80 (4%)	2.5246 (0.6066, 10.5078) /0.203	5.2052 (-2.7997, 13.2101) /0.202	2.3881 (0.6207, 9.1874) /0.205	
Myalgia						
White	9/216 (4%)	5/201 (2%)	1.7043 (0.5614, 5.1743) /0.347	1.6791 (-1.7469, 5.1051) /0.337	1.6750 (0.5710, 4.9137) /0.348	0.035
Non-White	5/ 67 (7%)	0/ 80	>999 (>999, >999) /NC	9.5226 (-13.7462, 32.7914) /0.422	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	6/216 (3%)	4/201 (2%)	1.4071 (0.3912, 5.0610) /0.601	0.7877 (-2.1330, 3.7084) /0.597	1.3958 (0.3997, 4.8743) /0.601	0.879
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	
Muscle contracture						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
White	4/216 (2%)	2/201 (<1%)	1.8774 (0.3401, 10.3629) /0.470	0.8568 (-1.4049, 3.1185) /0.458	1.8611 (0.3446, 10.0508) /0.470	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Musculoskeletal chest pain						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.455
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.385
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Neck pain						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondro sis						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tendonitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.900
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal discomfort						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Musculoskeletal stiffness						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Plantar fasciitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal disorder						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Spinal osteoarthritis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bursitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Intervertebral disc disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Osteonecrosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoporosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rotator cuff syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue mass						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Temporomandibular joint syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vertebral foraminal stenosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
White	49/216 (23%)	21/201 (10%)	2.5150 (1.4468, 4.3716) /0.001	12.2374 (5.2322, 19.2427) /<.001	2.1713 (1.3520, 3.4871) /0.001	0.380
Non-White	15/ 67 (22%)	12/ 80 (15%)	1.6346 (0.7053, 3.7886) /0.252	7.3881 (-5.2945, 20.0706) /0.254	1.4925 (0.7515, 2.9644) /0.253	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
White	31/216 (14%)	12/201 (6%)	2.6392 (1.3152, 5.2962) /0.006	8.3817 (2.6730, 14.0904) /0.004	2.4039 (1.2700, 4.5503) /0.007	0.143
Non-White	8/ 67 (12%)	9/ 80 (11%)	1.0697 (0.3884, 2.9458) /0.896	0.6903 (-9.7130, 11.0936) /0.897	1.0614 (0.4335, 2.5984) /0.896	
Dizziness						
White	11/216 (5%)	2/201 (<1%)	5.3390 (1.1686, 24.3919) /0.031	4.0976 (0.8605, 7.3346) /0.013	5.1181 (1.1485, 22.8081) /0.032	0.959
Non-White	4/ 67 (6%)	1/ 80 (1%)	5.0159 (0.5469, 46.0064) /0.154	4.7201 (-1.4535, 10.8938) /0.134	4.7761 (0.5469, 41.7109) /0.157	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Migraine						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Syncope						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Disturbance in attention						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lethargy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Poor quality sleep						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Somnolence						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anosmia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Autonomic nervous system imbalance						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical neuritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypoaesthesia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intercostal neuralgia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Nerve compression						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Radiculitis brachial						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Tremor						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Trigeminal neuralgia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Visual field defect						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	34/216 (16%)	23/201 (11%)	1.4458 (0.8192, 2.5516) /0.203	4.2980 (-2.2560, 10.8519) /0.199	1.3756 (0.8402, 2.2523) /0.205	0.631
Non-White	13/ 67 (19%)	9/ 80 (11%)	1.8992 (0.7564, 4.7686) /0.172	8.1530 (-3.5775, 19.8835) /0.173	1.7247 (0.7863, 3.7831) /0.174	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash						
White	2/216 (<1%)	7/201 (3%)	0.2590 (0.0532, 1.2618) /0.095	-2.5567 (-5.3949, 0.2816) /0.077	0.2659 (0.0559, 1.2648) /0.096	0.017
Non-White	4/ 67 (6%)	1/ 80 (1%)	5.0159 (0.5469, 46.0064) /0.154	4.7201 (-1.4535, 10.8938) /0.134	4.7761 (0.5469, 41.7109) /0.157	
Eczema						
White	6/216 (3%)	3/201 (1%)	1.8857 (0.4653, 7.6426) /0.374	1.2852 (-1.4739, 4.0444) /0.361	1.8611 (0.4717, 7.3427) /0.375	0.222
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Acne						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.611
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Seborrhoeic dermatitis						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dermatitis						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Erythema						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosi s						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Skin lesion						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Dyshidrotic eczema						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Night sweats						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papule						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Pityriasis						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash pruritic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Skin mass						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urticaria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Alopecia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood blister						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Dandruff						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis allergic						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Ephelides						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lipodystrophy acquired						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail pigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Penile ulceration						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pityriasis alba						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pruritus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Purpura						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Rash macular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash morbilliform						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rosacea						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin erosion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hyperpigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Skin hypopigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin induration						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Skin reaction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xeroderma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	34/216 (16%)	23/201 (11%)	1.4458 (0.8192, 2.5516) /0.203	4.2980 (-2.2560, 10.8519) /0.199	1.3756 (0.8402, 2.2523) /0.205	0.481
Non-White	9/ 67 (13%)	11/ 80 (14%)	0.9734 (0.3773, 2.5108) /0.955	-0.3172 (-11.4355, 10.8012) /0.955	0.9769 (0.4307, 2.2158) /0.955	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	6/216 (3%)	8/201 (4%)	0.6893 (0.2349, 2.0224) /0.498	-1.2023 (-4.6818, 2.2772) /0.498	0.6979 (0.2465, 1.9764) /0.498	0.537
Non-White	4/ 67 (6%)	4/ 80 (5%)	1.2063 (0.2900, 5.0187) /0.796	0.9701 (-6.4457, 8.3860) /0.798	1.1940 (0.3104, 4.5937) /0.796	
Oropharyngeal pain						
White	9/216 (4%)	3/201 (1%)	2.8696 (0.7657, 10.7536) /0.118	2.6741 (-0.4741, 5.8224) /0.096	2.7917 (0.7666, 10.1664) /0.120	0.849
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
White	8/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.110
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Catarrh						
White	5/216 (2%)	4/201 (2%)	1.1671 (0.3090, 4.4085) /0.820	0.3248 (-2.4590, 3.1085) /0.819	1.1632 (0.3168, 4.2710) /0.820	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.696
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	
Rhinorrhoea						
White	0/216	5/201 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Productive cough						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Sinus congestion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchial obstruction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bronchitis chronic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nasal dryness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal obstruction						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nasal turbinate hypertrophy						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Reflux laryngitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Throat irritation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tonsillar hypertrophy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Wheezing						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	26/216 (12%)	28/201 (14%)	0.8455 (0.4771, 1.4983) /0.565	-1.8933 (-8.3544, 4.5677) /0.566	0.8641 (0.5251, 1.4219) /0.565	0.651
Non-White	5/ 67 (7%)	9/ 80 (11%)	0.6362 (0.2024, 1.9994) /0.439	-3.7873 (-13.1435, 5.5688) /0.428	0.6633 (0.2335, 1.8841) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.066
Non-White	0/ 67	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-32.0243, 17.6830) /0.572	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Contusion						
White	7/216 (3%)	1/201 (<1%)	6.6985 (0.8168, 54.9332) /0.076	2.7432 (0.1892, 5.2972) /0.035	6.5139 (0.8085, 52.4784) /0.078	0.076
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Laceration						
White	4/216 (2%)	2/201 (<1%)	1.8774 (0.3401, 10.3629) /0.470	0.8568 (-1.4049, 3.1185) /0.458	1.8611 (0.3446, 10.0508) /0.470	0.344
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Thermal burn						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ankle fracture						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Fall						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Limb injury						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Meniscus injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Multiple injuries						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Procedural pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Wound						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Craniocerebral injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Exposure via inhalation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Heat stroke						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Joint dislocation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Neck injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile contusion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Post lumbar puncture syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rib fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Spinal column injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tendon injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tibia fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Traumatic haematoma						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral injury						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	33/216 (15%)	19/201 (9%)	1.7273 (0.9474, 3.1492) /0.074	5.8250 (-0.4501, 12.1002) /0.069	1.6162 (0.9506, 2.7479) /0.076	0.578
Non-White	8/ 67 (12%)	8/ 80 (10%)	1.2203 (0.4319, 3.4480) /0.707	1.9403 (-8.2333, 12.1139) /0.709	1.1940 (0.4736, 3.0102) /0.707	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	9/216 (4%)	6/201 (3%)	1.4130 (0.4938, 4.0434) /0.519	1.1816 (-2.3731, 4.7363) /0.515	1.3958 (0.5059, 3.8515) /0.520	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Body temperature increased						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.878
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
White	2/216 (<1%)	4/201 (2%)	0.4603 (0.0834, 2.5407) /0.373	-1.0641 (-3.3791, 1.2509) /0.368	0.4653 (0.0862, 2.5127) /0.374	0.135
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Vitamin D decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.345
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Weight decreased						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose abnormal						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Transaminases increased						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Blood cholesterol increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Blood folate decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Carbon dioxide decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Haemoglobin decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heart rate increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatic enzyme increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Mycoplasma test positive						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Platelet count decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Protein urine present						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Total lung capacity decreased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Treponema test positive						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Weight increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	27/216 (13%)	17/201 (8%)	1.5462 (0.8154, 2.9320) /0.182	4.0423 (-1.8100, 9.8945) /0.176	1.4779 (0.8311, 2.6281) /0.183	0.813
Non-White	11/ 67 (16%)	10/ 80 (13%)	1.3750 (0.5449, 3.4699) /0.500	3.9179 (-7.5363, 15.3721) /0.503	1.3134 (0.5946, 2.9012) /0.500	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
White	11/216 (5%)	5/201 (2%)	2.1034 (0.7178, 6.1636) /0.175	2.6050 (-1.0325, 6.2426) /0.160	2.0472 (0.7239, 5.7893) /0.177	0.907
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Insomnia						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	0.388
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	0.869
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Abnormal dreams						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	0.482
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.317
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.221
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Adjustment disorder						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Nightmare						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Suicidal ideation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Affect lability						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affective disorder						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Anxiety disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Intentional self-injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Paranoia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	21/216 (10%)	16/201 (8%)	1.2452 (0.6303, 2.4598) /0.528	1.7620 (-3.6796, 7.2037) /0.526	1.2214 (0.6561, 2.2736) /0.528	0.341
Non-White	12/ 67 (18%)	7/ 80 (9%)	2.2753 (0.8407, 6.1583) /0.106	9.1604 (-1.9137, 20.2346) /0.105	2.0469 (0.8543, 4.9044) /0.108	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Vitamin D deficiency						
White	15/216 (7%)	8/201 (4%)	1.8004 (0.7464, 4.3427) /0.191	2.9643 (-1.3712, 7.2999) /0.180	1.7448 (0.7560, 4.0266) /0.192	0.896
Non-White	8/ 67 (12%)	5/ 80 (6%)	2.0339 (0.6324, 6.5417) /0.234	5.6903 (-3.7130, 15.0936) /0.236	1.9104 (0.6558, 5.5650) /0.235	
Hypophosphat aemia						
White	0/216	4/201 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypovitaminosis						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypercholesterolaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.345
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.268
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Hyperlipasae mia						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertriglyceridaemia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Diabetes mellitus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diabetic ketoacidosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Glucose tolerance impaired						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gout						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypocalcaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Hypomagnesaemia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Iron deficiency						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	19/216 (9%)	17/201 (8%)	1.0439 (0.5265, 2.0698) /0.902	0.3386 (-5.0526, 5.7298) /0.902	1.0400 (0.5564, 1.9440) /0.902	0.346
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	9/216 (4%)	5/201 (2%)	1.7043 (0.5614, 5.1743) /0.347	1.6791 (-1.7469, 5.1051) /0.337	1.6750 (0.5710, 4.9137) /0.348	0.534
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	
Skin papilloma						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lipoma						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Melanocytic naevus						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Oral papilloma						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Uterine leiomyoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Adenocarcinoma of colon						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal neoplasm						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Benign spleen tumour						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dysplastic naevus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Kidney angiomyolipoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasm skin						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Oral fibroma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin cancer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	14/216 (6%)	13/201 (6%)	1.0023 (0.4592, 2.1878) /0.995	0.0138 (-4.7128, 4.7405) /0.995	1.0021 (0.4829, 2.0796) /0.995	0.807
Non-White	5/ 67 (7%)	5/ 80 (6%)	1.2097 (0.3348, 4.3701) /0.771	1.2127 (-7.0171, 9.4425) /0.773	1.1940 (0.3610, 3.9498) /0.771	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	0.383
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.127
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Breast mass						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.041
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genital lesion						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Breast pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervix disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dysfunctional uterine bleeding						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoea ^a						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Menopausal symptoms						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Ovarian cyst						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Polymenorrhoea						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Testicular pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Vaginal dysplasia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal haemorrhage						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vaginal ulceration						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vulvar dysplasia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	13/216 (6%)	8/201 (4%)	1.5449 (0.6266, 3.8095) /0.345	2.0384 (-2.1285, 6.2054) /0.338	1.5122 (0.6402, 3.5718) /0.346	0.827
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	0.304
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.181
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.236
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypochromic anaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lymphadenitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Normocytic anaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Splenomegaly						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	10/216 (5%)	6/201 (3%)	1.5777 (0.5627, 4.4231) /0.386	1.6446 (-2.0143, 5.3034) /0.378	1.5509 (0.5741, 4.1895) /0.387	0.782
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.161
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Proteinuria						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal failure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Calculus urinary						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glomerulonephritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Micturition urgency						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nephropathy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Urethral caruncle						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Urethral pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary incontinence						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
White	10/216 (5%)	4/201 (2%)	2.3908 (0.7377, 7.7484) /0.146	2.6396 (-0.7634, 6.0425) /0.128	2.3264 (0.7414, 7.2997) /0.148	0.172
Non-White	2/ 67 (3%)	4/ 80 (5%)	0.5846 (0.1037, 3.2956) /0.543	-2.0149 (-8.2929, 4.2630) /0.529	0.5970 (0.1128, 3.1590) /0.544	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Asthenopia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Blepharospasm						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chalazion White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chorioretinal disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Conjunctivitis allergic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic retinopathy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dry eye						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Eye irritation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Eye pruritus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Glare						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Glaucoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lacrimation increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Meibomian gland dysfunction						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Uveitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	9/216 (4%)	5/201 (2%)	1.7043 (0.5614, 5.1743) /0.347	1.6791 (-1.7469, 5.1051) /0.337	1.6750 (0.5710, 4.9137) /0.348	0.823
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.296
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.317
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cerumen impaction						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hypoacusis						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Deafness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective myringitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tinnitus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	8/216 (4%)	3/201 (1%)	2.5385 (0.6640, 9.7051) /0.173	2.2112 (-0.8142, 5.2365) /0.152	2.4815 (0.6676, 9.2237) /0.175	0.978
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertension						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.638
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Circulatory collapse						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Intermittent claudication						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral artery thrombosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Peripheral ischaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral venous disease						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Thrombophlebitis superficial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	7/216 (3%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.025
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.306
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Mite allergy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	6/216 (3%)	1/201 (<1%)	5.7142 (0.6819, 47.8846) /0.108	2.2803 (-0.1174, 4.6780) /0.062	5.5833 (0.6781, 45.9731) /0.110	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperbilirubinaemia						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Cholecystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatic cirrhosis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic steatosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatitis toxic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hydrocholecystis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Non-alcoholic steatohepatitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrioventricular block first degree						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Goitre						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypothyroidism						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Keratosis follicular						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tooth extraction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	43/ 47 (91%)	43/ 62 (69%)	4.7500 (1.4919, 15.1236) /0.008	22.1345 (8.1586, 36.1105) /0.002	1.3191 (1.0941, 1.5904) /0.004	0.183
Europe	204/213 (96%)	157/192 (82%)	5.0531 (2.3596, 10.8211) /<.001	14.0038 (7.9110, 20.0966) /<.001	1.1713 (1.0893, 1.2593) /<.001	
Rest of World	20/ 23 (87%)	25/ 29 (86%)	1.0667 (0.2136, 5.3272) /0.937	0.7496 (-17.8768, 19.3761) /0.937	1.0087 (0.8135, 1.2507) /0.937	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	30/ 47 (64%)	35/ 62 (56%)	1.3613 (0.6250, 2.9653) /0.437	7.3782 (-11.0885, 25.8449) /0.434	1.1307 (0.8320, 1.5367) /0.433	0.833
Europe	149/213 (70%)	121/192 (63%)	1.3661 (0.9027, 2.0674) /0.140	6.9322 (-2.2620, 16.1265) /0.139	1.1100 (0.9654, 1.2763) /0.143	
Rest of World	17/ 23 (74%)	17/ 29 (59%)	2.0000 (0.6094, 6.5637) /0.253	15.2924 (-10.0722, 40.6569) /0.237	1.2609 (0.8533, 1.8631) /0.245	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	2/ 47 (4%)	6/ 62 (10%)	0.4148 (0.0798, 2.1550) /0.295	-5.4221 (-14.7740, 3.9298) /0.256	0.4397 (0.0929, 2.0816) /0.300	0.401
Europe	51/213 (24%)	38/192 (20%)	1.2758 (0.7939, 2.0504) /0.314	4.1520 (-3.8857, 12.1897) /0.311	1.2098 (0.8340, 1.7549) /0.316	
Rest of World	3/ 23 (13%)	4/ 29 (14%)	0.9375 (0.1877, 4.6821) /0.937	-0.7496 (-19.3761, 17.8768) /0.937	0.9457 (0.2348, 3.8093) /0.937	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	14/ 47 (30%)	17/ 62 (27%)	1.1230 (0.4858, 2.5959) /0.786	2.3679 (-14.7857, 19.5215) /0.787	1.0864 (0.5979, 1.9740) /0.786	0.178
Europe	17/213 (8%)	5/192 (3%)	3.2439 (1.1732, 8.9695) /0.023	5.3771 (1.0969, 9.6572) /0.014	3.0648 (1.1527, 8.1486) /0.025	
Rest of World	7/ 23 (30%)	6/ 29 (21%)	1.6771 (0.4741, 5.9325) /0.422	9.7451 (-14.1500, 33.6402) /0.424	1.4710 (0.5728, 3.7777) /0.423	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza North America	4/ 47 (9%)	3/ 62 (5%)	1.8295 (0.3892, 8.5994) /0.444	3.6719 (-5.9286, 13.2724) /0.453	1.7589 (0.4133, 7.4844) /0.445	0.301
Europe	20/213 (9%)	13/192 (7%)	1.4269 (0.6895, 2.9528) /0.338	2.6188 (-2.6702, 7.9079) /0.332	1.3868 (0.7093, 2.7114) /0.339	
Rest of World	1/ 23 (4%)	4/ 29 (14%)	0.2841 (0.0295, 2.7360) /0.276	-9.4453 (-24.5107, 5.6202) /0.219	0.3152 (0.0378, 2.6310) /0.286	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.372
Europe	14/213 (7%)	8/192 (4%)	1.6181 (0.6635, 3.9461) /0.290	2.4061 (-1.9601, 6.7723) /0.280	1.5775 (0.6766, 3.6777) /0.291	
Rest of World	1/ 23 (4%)	2/ 29 (7%)	0.6136 (0.0521, 7.2227) /0.698	-2.5487 (-14.9791, 9.8817) /0.688	0.6304 (0.0609, 6.5267) /0.699	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	13/213 (6%)	12/192 (6%)	0.9750 (0.4337, 2.1918) /0.951	-0.1467 (-4.8434, 4.5500) /0.951	0.9765 (0.4567, 2.0880) /0.951	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
North America	0/ 47	0/ 62	NC	NC	NC	0.665
Europe	12/213 (6%)	8/192 (4%)	1.3731 (0.5490, 3.4342) /0.498	1.4671 (-2.7254, 5.6597) /0.493	1.3521 (0.5647, 3.2373) /0.498	
Rest of World	3/ 23 (13%)	1/ 29 (3%)	4.2000 (0.4067, 43.3743) /0.228	9.5952 (-5.6868, 24.8772) /0.218	3.7826 (0.4208, 34.0020) /0.235	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.990
Europe	10/213 (5%)	8/192 (4%)	1.1330 (0.4378, 2.9321) /0.797	0.5282 (-3.4792, 4.5355) /0.796	1.1268 (0.4540, 2.7964) /0.797	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	0.154
Europe	10/213 (5%)	7/192 (4%)	1.3019 (0.4856, 3.4905) /0.600	1.0490 (-2.8366, 4.9346) /0.597	1.2877 (0.5000, 3.3163) /0.600	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	11/213 (5%)	6/192 (3%)	1.6881 (0.6121, 4.6556) /0.312	2.0393 (-1.8194, 5.8981) /0.300	1.6526 (0.6231, 4.3830) /0.313	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.869
Europe	10/213 (5%)	3/192 (2%)	3.1034 (0.8413, 11.4483) /0.089	3.1323 (-0.2064, 6.4710) /0.066	3.0047 (0.8393, 10.7570) /0.091	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.438
Europe	6/213 (3%)	3/192 (2%)	1.8261 (0.4504, 7.4041) /0.399	1.2544 (-1.5766, 4.0854) /0.385	1.8028 (0.4571, 7.1097) /0.400	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	>0.999
Europe	7/213 (3%)	5/192 (3%)	1.2709 (0.3966, 4.0726) /0.687	0.6822 (-2.6052, 3.9696) /0.684	1.2620 (0.4073, 3.9103) /0.687	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	8/213 (4%)	5/192 (3%)	1.4595 (0.4692, 4.5399) /0.514	1.1517 (-2.2533, 4.5567) /0.507	1.4423 (0.4800, 4.3336) /0.514	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	8/192 (4%)	0.5529 (0.1777, 1.7198) /0.306	-1.8192 (-5.3011, 1.6626) /0.306	0.5634 (0.1875, 1.6928) /0.307	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
North America	0/ 47	4/ 62 (6%)	<0.0001 (<0.0001, -) />0.999	-8.5579 (-38.2183, 21.1025) /0.572	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	5/192 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.995
Europe	5/213 (2%)	4/192 (2%)	1.1298 (0.2990, 4.2697) /0.857	0.2641 (-2.6022, 3.1304) /0.857	1.1268 (0.3070, 4.1354) /0.857	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	3/192 (2%)	2.1408 (0.5457, 8.3981) /0.275	1.7239 (-1.2442, 4.6920) /0.255	2.1033 (0.5516, 8.0194) /0.276	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.300
Europe	2/213 (<1%)	3/192 (2%)	0.5972 (0.0987, 3.6123) /0.575	-0.6235 (-2.8041, 1.5570) /0.575	0.6009 (0.1015, 3.5583) /0.575	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.396
Europe	5/213 (2%)	2/192 (1%)	2.2837 (0.4379, 11.9097) /0.327	1.3058 (-1.1835, 3.7950) /0.304	2.2535 (0.4423, 11.4808) /0.328	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes zoster						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	5/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	6/213 (3%)	2/192 (1%)	2.7536 (0.5491, 13.8086) /0.218	1.7752 (-0.8704, 4.4209) /0.188	2.7042 (0.5524, 13.2393) /0.220	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.553
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.514
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.252
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.252
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.336
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal candidiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanitis candida						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis externa						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vulvovaginitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis pneumococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cat scratch disease						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dacryocystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis shigella						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital candidiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary chlamydia infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract gonococcal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter gastritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Infectious colitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lice infestation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranuloma venereum						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oophoritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis mycoplasmal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis chronic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Strongyloidi- asis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis mycoplasmal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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General disorders and administration site conditions						
Any Event						
North America	39/ 47 (83%)	6/ 62 (10%)	45.4999 (14.6292, 141.5143) /<.001	73.3013 (60.2783, 86.3243) /<.001	8.5745 (3.9646, 18.5447) /<.001	NC
Europe	190/213 (89%)	19/192 (10%)	75.2173 (39.5989, 142.8737) /<.001	79.3060 (73.3721, 85.2400) /<.001	9.0141 (5.8674, 13.8482) /<.001	
Rest of World	14/ 23 (61%)	1/ 29 (3%)	43.5556 (5.0065, 378.9251) /<.001	57.4213 (36.3994, 78.4432) /<.001	17.6521 (2.5025, 124.5125) /0.004	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	37/ 47 (79%)	0/ 62	>999 (>999, >999) /NC	77.3233 (49.5852, 105.0614) /<.001	NC	NC
Europe	178/213 (84%)	0/192	>999 (>999, >999) /NC	NC	NC	
Rest of World	12/ 23 (52%)	0/ 29	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	5/ 47 (11%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	38/213 (18%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site induration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	38/213 (18%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	16/213 (8%)	4/192 (2%)	3.8173 (1.2533, 11.6262) /0.018	5.4284 (1.3527, 9.5041) /0.009	3.6056 (1.2267, 10.5978) /0.020	
Rest of World	4/ 23 (17%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	3/ 47 (6%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	20/213 (9%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
North America	4/ 47 (9%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	12/213 (6%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	3/ 47 (6%)	2/ 62 (3%)	2.0455 (0.3278, 12.7638) /0.444	3.1572 (-5.1001, 11.4144) /0.454	1.9787 (0.3443, 11.3705) /0.444	0.546
Europe	4/213 (2%)	6/192 (3%)	0.5933 (0.1649, 2.1349) /0.424	-1.2471 (-4.3098, 1.8157) /0.425	0.6009 (0.1722, 2.0975) /0.425	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	8/213 (4%)	7/192 (4%)	1.0314 (0.3669, 2.8995) /0.953	0.1100 (-3.5707, 3.7908) /0.953	1.0302 (0.3807, 2.7876) /0.953	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

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Asthenia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	12/213 (6%)	1/192 (<1%)	11.4029 (1.4686, 88.5397) /0.020	5.1130 (1.8534, 8.3725) /0.002	10.8169 (1.4197, 82.4143) /0.022	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site erythema						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	10/213 (5%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site warmth						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	7/213 (3%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Malaise North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 23 (13%)	1/ 29 (3%)	4.2000 (0.4067, 43.3743) /0.228	9.5952 (-5.6868, 24.8772) /0.218	3.7826 (0.4208, 34.0020) /0.235	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site bruising						
North America	5/ 47 (11%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Discomfort North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site haematoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nodule North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catheter site erythema						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site granuloma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site necrosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site scar						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Swelling North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Systemic inflammatory response syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site bruise						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Gastrointestinal disorders						
Any Event						
North America	17/ 47 (36%)	14/ 62 (23%)	1.9429 (0.8373, 4.5080) /0.122	13.5896 (-3.6446, 30.8237) /0.122	1.6018 (0.8816, 2.9106) /0.122	0.008
Europe	85/213 (40%)	47/192 (24%)	2.0487 (1.3350, 3.1440) /0.001	15.4269 (6.4694, 24.3845) /<.001	1.6302 (1.2099, 2.1964) /0.001	
Rest of World	5/ 23 (22%)	14/ 29 (48%)	0.2976 (0.0870, 1.0179) /0.053	-26.5367 (-51.3343, -1.7391) /0.036	0.4503 (0.1902, 1.0664) /0.070	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	4/ 47 (9%)	4/ 62 (6%)	1.3488 (0.3193, 5.6984) /0.684	2.0590 (-7.9926, 12.1106) /0.688	1.3191 (0.3478, 5.0030) /0.684	0.551
Europe	27/213 (13%)	18/192 (9%)	1.4032 (0.7464, 2.6379) /0.293	3.3011 (-2.7786, 9.3807) /0.287	1.3521 (0.7696, 2.3756) /0.294	
Rest of World	1/ 23 (4%)	3/ 29 (10%)	0.3939 (0.0382, 4.0623) /0.434	-5.9970 (-19.8648, 7.8708) /0.397	0.4203 (0.0468, 3.7780) /0.439	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
North America	6/ 47 (13%)	4/ 62 (6%)	2.1220 (0.5630, 7.9980) /0.266	6.3143 (-5.0177, 17.6464) /0.275	1.9787 (0.5918, 6.6159) /0.268	0.017
Europe	10/213 (5%)	3/192 (2%)	3.1034 (0.8413, 11.4483) /0.089	3.1323 (-0.2064, 6.4710) /0.066	3.0047 (0.8393, 10.7570) /0.091	
Rest of World	0/ 23	4/ 29 (14%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	3/ 47 (6%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.067
Europe	8/213 (4%)	5/192 (3%)	1.4595 (0.4692, 4.5399) /0.514	1.1517 (-2.2533, 4.5567) /0.507	1.4423 (0.4800, 4.3336) /0.514	
Rest of World	1/ 23 (4%)	3/ 29 (10%)	0.3939 (0.0382, 4.0623) /0.434	-5.9970 (-19.8648, 7.8708) /0.397	0.4203 (0.0468, 3.7780) /0.439	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	3/ 47 (6%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.348
Europe	12/213 (6%)	3/192 (2%)	3.7612 (1.0451, 13.5363) /0.043	4.0713 (0.5124, 7.6302) /0.025	3.6056 (1.0330, 12.5852) /0.044	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	7/213 (3%)	4/192 (2%)	1.5971 (0.4602, 5.5426) /0.461	1.2031 (-1.9296, 4.3357) /0.452	1.5775 (0.4690, 5.3053) /0.461	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	8/213 (4%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	5/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	2/ 29 (7%)	0.6136 (0.0521, 7.2227) /0.698	-2.5487 (-14.9791, 9.8817) /0.688	0.6304 (0.0609, 6.5267) /0.699	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	5/213 (2%)	3/192 (2%)	1.5144 (0.3571, 6.4229) /0.573	0.7849 (-1.9005, 3.4703) /0.567	1.5023 (0.3639, 6.2030) /0.574	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	2/192 (1%)	3.2282 (0.6624, 15.7320) /0.147	2.2447 (-0.5472, 5.0366) /0.115	3.1549 (0.6634, 15.0035) /0.149	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.852
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis North America	0/ 47	0/ 62	NC	NC	NC	0.999
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	2/192 (1%)	1.8182 (0.3293, 10.0397) /0.493	0.8363 (-1.4844, 3.1570) /0.480	1.8028 (0.3339, 9.7326) /0.493	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.204
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	3/192 (2%)	0.5972 (0.0987, 3.6123) /0.575	-0.6235 (-2.8041, 1.5570) /0.575	0.6009 (0.1015, 3.5583) /0.575	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal 1 haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Abdominal distension						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal inflammation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea haemorrhagic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroduodenitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival bleeding						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Inguinal hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lip dry						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Stomatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Aerophagia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal fistula						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
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Aphthous ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Barrett's oesophagus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile acid malabsorption						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Bowel movement irregularity						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis microscopic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysbacteriosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal sounds abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival swelling						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematochezi ^a						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oesophageal polyp						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palatal ulcer						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia oral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth development disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	8/ 47 (17%)	12/ 62 (19%)	0.8547 (0.3183, 2.2950) /0.755	-2.3336 (-16.8989, 12.2318) /0.754	0.8794 (0.3911, 1.9775) /0.756	0.402
Europe	52/213 (24%)	29/192 (15%)	1.8154 (1.0970, 3.0043) /0.020	9.3090 (1.6320, 16.9859) /0.017	1.6163 (1.0724, 2.4361) /0.022	
Rest of World	4/ 23 (17%)	3/ 29 (10%)	1.8246 (0.3649, 9.1242) /0.464	7.0465 (-12.0011, 26.0940) /0.468	1.6812 (0.4173, 6.7721) /0.465	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	3/ 47 (6%)	1/ 62 (2%)	4.1591 (0.4186, 41.3233) /0.224	4.7701 (-2.8897, 12.4299) /0.222	3.9574 (0.4250, 36.8479) /0.227	0.671
Europe	18/213 (8%)	11/192 (6%)	1.5189 (0.6984, 3.3031) /0.292	2.7215 (-2.2543, 7.6974) /0.284	1.4750 (0.7149, 3.0434) /0.293	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.149
Europe	12/213 (6%)	4/192 (2%)	2.8060 (0.8894, 8.8523) /0.078	3.5505 (-0.1468, 7.2477) /0.060	2.7042 (0.8871, 8.2438) /0.080	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.464
Europe	7/213 (3%)	4/192 (2%)	1.5971 (0.4602, 5.5426) /0.461	1.2031 (-1.9296, 4.3357) /0.452	1.5775 (0.4690, 5.3053) /0.461	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
North America	3/ 47 (6%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteochondro sis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.982
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal discomfort						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal stiffness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoporosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	9/ 47 (19%)	4/ 62 (6%)	3.4342 (0.9871, 11.9483) /0.052	12.6973 (-0.1064, 25.5010) /0.052	2.9681 (0.9732, 9.0525) /0.056	0.576
Europe	49/213 (23%)	26/192 (14%)	1.9076 (1.1316, 3.2158) /0.015	9.4630 (2.0220, 16.9041) /0.013	1.6988 (1.1010, 2.6212) /0.017	
Rest of World	6/ 23 (26%)	3/ 29 (10%)	3.0588 (0.6725, 13.9123) /0.148	15.7421 (-5.3505, 36.8347) /0.144	2.5217 (0.7059, 9.0091) /0.155	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	4/ 47 (9%)	2/ 62 (3%)	2.7907 (0.4889, 15.9309) /0.248	5.2848 (-3.8246, 14.3943) /0.256	2.6383 (0.5044, 13.7996) /0.250	0.808
Europe	32/213 (15%)	16/192 (8%)	1.9448 (1.0306, 3.6697) /0.040	6.6901 (0.5008, 12.8795) /0.034	1.8028 (1.0221, 3.1800) /0.042	
Rest of World	3/ 23 (13%)	3/ 29 (10%)	1.3000 (0.2367, 7.1387) /0.763	2.6987 (-14.9732, 20.3705) /0.765	1.2609 (0.2803, 5.6725) /0.763	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness North America	4/ 47 (9%)	1/ 62 (2%)	5.6744 (0.6127, 52.5494) /0.126	6.8977 (-1.6739, 15.4693) /0.115	5.2766 (0.6096, 45.6750) /0.131	NC
Europe	11/213 (5%)	2/192 (1%)	5.1733 (1.1319, 23.6439) /0.034	4.1227 (0.8219, 7.4235) /0.014	4.9577 (1.1129, 22.0852) /0.036	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anosmia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical neuritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nerve compression						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tremor North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigeminal neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Visual field defect						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	8/ 47 (17%)	8/ 62 (13%)	1.3846 (0.4783, 4.0086) /0.549	4.1181 (-9.4861, 17.7222) /0.553	1.3191 (0.5343, 3.2566) /0.548	0.723
Europe	35/213 (16%)	19/192 (10%)	1.7904 (0.9861, 3.2506) /0.056	6.5361 (0.0088, 13.0634) /0.050	1.6605 (0.9839, 2.8024) /0.058	
Rest of World	4/ 23 (17%)	5/ 29 (17%)	1.0105 (0.2380, 4.2908) /0.989	0.1499 (-20.5615, 20.8613) /0.989	1.0087 (0.3052, 3.3339) /0.989	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
North America	2/ 47 (4%)	3/ 62 (5%)	0.8741 (0.1401, 5.4530) /0.885	-0.5834 (-8.4466, 7.2798) /0.884	0.8794 (0.1530, 5.0536) /0.885	0.327
Europe	3/213 (1%)	5/192 (3%)	0.5343 (0.1260, 2.2660) /0.395	-1.1957 (-3.9487, 1.5573) /0.395	0.5408 (0.1310, 2.2331) /0.396	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	3/192 (2%)	2.1408 (0.5457, 8.3981) /0.275	1.7239 (-1.2442, 4.6920) /0.255	2.1033 (0.5516, 8.0194) /0.276	
Rest of World	0/ 23	3/ 29 (10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Dermatitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosi s						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dyshidrotic eczema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papule North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pruritus generalised						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rash pruritic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Dermatitis allergic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ephelides North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Granuloma annulare						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipodystrophy acquired						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail pigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pityriasis alba						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash morbilliform						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin erosion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hyperpigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hypopigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin induration						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin reaction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Xeroderma North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	6/ 47 (13%)	9/ 62 (15%)	0.8618 (0.2839, 2.6163) /0.793	-1.7502 (-14.7080, 11.2076) /0.791	0.8794 (0.3364, 2.2989) /0.793	0.243
Europe	35/213 (16%)	20/192 (10%)	1.6910 (0.9392, 3.0445) /0.080	6.0153 (-0.5753, 12.6058) /0.074	1.5775 (0.9439, 2.6364) /0.082	
Rest of World	2/ 23 (9%)	5/ 29 (17%)	0.4571 (0.0801, 2.6078) /0.378	-8.5457 (-26.4794, 9.3879) /0.350	0.5043 (0.1075, 2.3663) /0.385	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough North America	2/ 47 (4%)	5/ 62 (8%)	0.5067 (0.0939, 2.7342) /0.429	-3.8092 (-12.7107, 5.0923) /0.402	0.5277 (0.1070, 2.6015) /0.432	0.183
Europe	8/213 (4%)	5/192 (3%)	1.4595 (0.4692, 4.5399) /0.514	1.1517 (-2.2533, 4.5567) /0.507	1.4423 (0.4800, 4.3336) /0.514	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.257
Europe	10/213 (5%)	2/192 (1%)	4.6798 (1.0123, 21.6342) /0.048	3.6532 (0.4701, 6.8363) /0.024	4.5070 (1.0000, 20.3126) /0.050	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	7/213 (3%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	4/192 (2%)	1.1298 (0.2990, 4.2697) /0.857	0.2641 (-2.6022, 3.1304) /0.857	1.1268 (0.3070, 4.1354) /0.857	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rhinorrhoea						
North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	3/192 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Productive cough						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Respiratory disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Sinus congestion						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Bronchial obstruction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Bronchitis chronic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nasal obstruction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal turbinate hypertrophy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reflux laryngitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Throat irritation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillar hypertrophy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	6/ 47 (13%)	7/ 62 (11%)	1.1498 (0.3594, 3.6789) /0.814	1.4756 (-10.8968, 13.8480) /0.815	1.1307 (0.4067, 3.1432) /0.814	0.296
Europe	25/213 (12%)	28/192 (15%)	0.7789 (0.4367, 1.3891) /0.397	-2.8462 (-9.4497, 3.7572) /0.398	0.8048 (0.4868, 1.3307) /0.397	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.210
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	7/213 (3%)	1/192 (<1%)	6.4903 (0.7912, 53.2403) /0.082	2.7656 (0.1638, 5.3673) /0.037	6.3099 (0.7834, 50.8207) /0.084	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.852
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	3/192 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ankle fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cranio-cerebral injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure via inhalation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fracture North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile contusion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tibia fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Traumatic haematoma						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	3/ 47 (6%)	5/ 62 (8%)	0.7773 (0.1762, 3.4296) /0.739	-1.6815 (-11.4169, 8.0538) /0.735	0.7915 (0.1991, 3.1469) /0.740	0.445
Europe	35/213 (16%)	18/192 (9%)	1.9007 (1.0373, 3.4831) /0.038	7.0569 (0.5944, 13.5194) /0.032	1.7527 (1.0276, 2.9896) /0.039	
Rest of World	3/ 23 (13%)	4/ 29 (14%)	0.9375 (0.1877, 4.6821) /0.937	-0.7496 (-19.3761, 17.8768) /0.937	0.9457 (0.2348, 3.8093) /0.937	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.998
Europe	8/213 (4%)	5/192 (3%)	1.4595 (0.4692, 4.5399) /0.514	1.1517 (-2.2533, 4.5567) /0.507	1.4423 (0.4800, 4.3336) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	9/213 (4%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.235
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood folate decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heart rate increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma test positive						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Platelet count decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Protein urine present						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Total lung capacity decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Treponema test positive						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	7/ 47 (15%)	7/ 62 (11%)	1.3750 (0.4468, 4.2312) /0.579	3.6033 (-9.2674, 16.4740) /0.583	1.3191 (0.4967, 3.5031) /0.578	0.871
Europe	29/213 (14%)	19/192 (10%)	1.4351 (0.7762, 2.6533) /0.249	3.7192 (-2.5299, 9.9683) /0.243	1.3758 (0.7981, 2.3719) /0.251	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	13/213 (6%)	4/192 (2%)	3.0550 (0.9788, 9.5351) /0.054	4.0200 (0.2230, 7.8169) /0.038	2.9296 (0.9717, 8.8322) /0.056	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.277
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.251
Europe	5/213 (2%)	3/192 (2%)	1.5144 (0.3571, 6.4229) /0.573	0.7849 (-1.9005, 3.4703) /0.567	1.5023 (0.3639, 6.2030) /0.574	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affect lability						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affective disorder						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paranoia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	7/ 47 (15%)	6/ 62 (10%)	1.6333 (0.5103, 5.2283) /0.409	5.2162 (-7.3440, 17.7764) /0.416	1.5390 (0.5536, 4.2783) /0.409	0.864
Europe	24/213 (11%)	16/192 (8%)	1.3968 (0.7183, 2.7163) /0.325	2.9343 (-2.8376, 8.7062) /0.319	1.3521 (0.7408, 2.4680) /0.326	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	5/ 47 (11%)	3/ 62 (5%)	2.3413 (0.5303, 10.3371) /0.262	5.7996 (-4.5072, 16.1064) /0.270	2.1986 (0.5530, 8.7413) /0.263	0.921
Europe	17/213 (8%)	9/192 (5%)	1.7636 (0.7669, 4.0554) /0.182	3.2937 (-1.4163, 8.0037) /0.170	1.7027 (0.7773, 3.7294) /0.183	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	4/192 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypovitaminosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasae mia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glucose tolerance impaired						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypocalcaemi ^a						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypomagnesemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.133
Europe	22/213 (10%)	15/192 (8%)	1.3592 (0.6835, 2.7028) /0.382	2.5161 (-3.0618, 8.0941) /0.377	1.3221 (0.7065, 2.4740) /0.383	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital warts						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	12/213 (6%)	5/192 (3%)	2.2328 (0.7720, 6.4584) /0.138	3.0296 (-0.7996, 6.8588) /0.121	2.1634 (0.7763, 6.0288) /0.140	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral papilloma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal neoplasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign spleen tumour						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cancer						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysplastic naevus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kaposi's sarcoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kidney angiomyolipoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Neoplasm skin						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oral fibroma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin cancer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

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Reproductive system and breast disorders						
Any Event						
North America	3/ 47 (6%)	3/ 62 (5%)	1.3409 (0.2582, 6.9628) /0.727	1.5443 (-7.2517, 10.3403) /0.731	1.3191 (0.2787, 6.2448) /0.727	0.273
Europe	16/213 (8%)	13/192 (7%)	1.1183 (0.5234, 2.3896) /0.773	0.7409 (-4.2750, 5.7568) /0.772	1.1094 (0.5480, 2.2461) /0.773	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.784
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrophic vulvovaginitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital lesion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast discharge						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe ^a						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopausal symptoms						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstruation irregular						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polymenorrhoea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal ulceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvar dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	3/ 47 (6%)	2/ 62 (3%)	2.0455 (0.3278, 12.7638) /0.444	3.1572 (-5.1001, 11.4144) /0.454	1.9787 (0.3443, 11.3705) /0.444	0.879
Europe	12/213 (6%)	9/192 (5%)	1.2139 (0.4999, 2.9477) /0.668	0.9463 (-3.3580, 5.2506) /0.667	1.2019 (0.5178, 2.7895) /0.669	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	0.855
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	3/192 (2%)	0.5972 (0.0987, 3.6123) /0.575	-0.6235 (-2.8041, 1.5570) /0.575	0.6009 (0.1015, 3.5583) /0.575	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypochromic anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Normocytic anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splenomegaly						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.232
Europe	11/213 (5%)	9/192 (5%)	1.1073 (0.4487, 2.7326) /0.825	0.4768 (-3.7388, 4.6925) /0.825	1.1017 (0.4666, 2.6011) /0.825	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	2/192 (1%)	2.2837 (0.4379, 11.9097) /0.327	1.3058 (-1.1835, 3.7950) /0.304	2.2535 (0.4423, 11.4808) /0.328	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Calculus urinary						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerulonephritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral caruncle						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary incontinence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.103
Europe	11/213 (5%)	4/192 (2%)	2.5594 (0.8012, 8.1764) /0.113	3.0810 (-0.5127, 6.6746) /0.093	2.4789 (0.8027, 7.6556) /0.115	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenopia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blepharospasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chorioretinal disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic retinopathy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dry eye North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eye allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eye irritation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eye pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glare						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glaucoma North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meibomian gland dysfunction						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uveitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.035
Europe	9/213 (4%)	3/192 (2%)	2.7794 (0.7413, 10.4205) /0.130	2.6629 (-0.5583, 5.8840) /0.105	2.7042 (0.7429, 9.8436) /0.131	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.232
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Noninfective myringitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.140
Europe	8/213 (4%)	3/192 (2%)	2.4585 (0.6428, 9.4037) /0.189	2.1934 (-0.9045, 5.2912) /0.165	2.4038 (0.6470, 8.9309) /0.190	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.137
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Circulatory collapse						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intermittent claudication						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.563
Europe	8/213 (4%)	2/192 (1%)	3.7073 (0.7775, 17.6779) /0.100	2.7142 (-0.2153, 5.6437) /0.069	3.6056 (0.7752, 16.7712) /0.102	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.264
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypersensitivity						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mite allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hyperbilirubinaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bile duct stone						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Cholecystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hepatic cirrhosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic steatosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis toxic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocholestis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-alcoholic steatohepatitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Cardiovascular disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrioventricular block first degree						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Goitre						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gilbert's syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Keratosis follicular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth extraction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	216/227 (95%)	180/227 (79%)	5.1273 (2.5830, 10.1777) /<.001	15.8590 (9.8936, 21.8245) /<.001	1.2000 (1.1159, 1.2904) /<.001	0.517
>=100,000	51/ 56 (91%)	45/ 56 (80%)	2.4933 (0.8050, 7.7229) /0.113	10.7143 (-2.0942, 23.5227) /0.101	1.1333 (0.9723, 1.3211) /0.109	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<100,000	157/227 (69%)	141/227 (62%)	1.3680 (0.9272, 2.0183) /0.114	7.0485 (-1.6645, 15.7614) /0.113	1.1135 (0.9742, 1.2727) /0.115	0.572
>=100,000	39/ 56 (70%)	32/ 56 (57%)	1.7206 (0.7907, 3.7442) /0.171	12.5000 (-5.1924, 30.1924) /0.166	1.2187 (0.9163, 1.6210) /0.174	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<100,000	48/227 (21%)	37/227 (16%)	1.3770 (0.8564, 2.2141) /0.187	4.8458 (-2.3169, 12.0085) /0.185	1.2973 (0.8807, 1.9109) /0.188	0.212
>=100,000	8/ 56 (14%)	11/ 56 (20%)	0.6818 (0.2515, 1.8486) /0.452	-5.3571 (-19.2234, 8.5092) /0.449	0.7273 (0.3165, 1.6712) /0.453	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<100,000	31/227 (14%)	19/227 (8%)	1.7315 (0.9470, 3.1659) /0.075	5.2863 (-0.4524, 11.0251) /0.071	1.6316 (0.9502, 2.8015) /0.076	0.169
>=100,000	7/ 56 (13%)	9/ 56 (16%)	0.7460 (0.2570, 2.1657) /0.590	-3.5714 (-16.5158, 9.3729) /0.589	0.7778 (0.3113, 1.9432) /0.591	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <100,000	21/227 (9%)	16/227 (7%)	1.3444 (0.6823, 2.6487) /0.392	2.2026 (-2.8267, 7.2320) /0.391	1.3125 (0.7033, 2.4492) /0.393	0.718
>=100,000	4/ 56 (7%)	4/ 56 (7%)	1.0000 (0.2373, 4.2132) />0.999	<0.0001 (-9.5392, 9.5392) />0.999	1.0000 (0.2630, 3.8019) />0.999	
Gastroenteritis <100,000	12/227 (5%)	9/227 (4%)	1.3519 (0.5582, 3.2743) /0.504	1.3216 (-2.5406, 5.1838) /0.502	1.3333 (0.5731, 3.1023) /0.504	0.905
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<100,000	12/227 (5%)	11/227 (5%)	1.0960 (0.4733, 2.5378) /0.831	0.4405 (-3.5938, 4.4749) /0.831	1.0909 (0.4916, 2.4210) /0.831	0.952
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis <100,000	10/227 (4%)	9/227 (4%)	1.1162 (0.4449, 2.8008) /0.815	0.4405 (-3.2432, 4.1243) /0.815	1.1111 (0.4602, 2.6829) /0.815	0.018
>=100,000	5/ 56 (9%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchitis <100,000	10/227 (4%)	7/227 (3%)	1.4483 (0.5414, 3.8741) /0.461	1.3216 (-2.1690, 4.8122) /0.458	1.4286 (0.5535, 3.6872) /0.461	0.448
>=100,000	2/ 56 (4%)	3/ 56 (5%)	0.6543 (0.1051, 4.0744) /0.649	-1.7857 (-9.4280, 5.8565) /0.647	0.6667 (0.1158, 3.8381) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Rhinitis						
<100,000	7/227 (3%)	6/227 (3%)	1.1720 (0.3877, 3.5430) /0.779	0.4405 (-2.6274, 3.5085) /0.778	1.1667 (0.3983, 3.4176) /0.779	0.630
>=100,000	3/ 56 (5%)	4/ 56 (7%)	0.7358 (0.1570, 3.4498) /0.697	-1.7857 (-10.7455, 7.1741) /0.696	0.7500 (0.1759, 3.1986) /0.697	
Syphilis						
<100,000	8/227 (4%)	5/227 (2%)	1.6219 (0.5224, 5.0352) /0.403	1.3216 (-1.7442, 4.3874) /0.398	1.6000 (0.5315, 4.8168) /0.403	0.436
>=100,000	4/ 56 (7%)	1/ 56 (2%)	4.2308 (0.4577, 39.1046) /0.204	5.3571 (-2.2277, 12.9419) /0.166	4.0000 (0.4614, 34.6768) /0.208	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <100,000	9/227 (4%)	3/227 (1%)	3.0826 (0.8236, 11.5380) /0.095	2.6432 (-0.2980, 5.5843) /0.078	3.0000 (0.8228, 10.9380) /0.096	0.772
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
Folliculitis <100,000	5/227 (2%)	4/227 (2%)	1.2556 (0.3328, 4.7374) /0.737	0.4405 (-2.1236, 3.0047) /0.736	1.2500 (0.3400, 4.5951) /0.737	0.870
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <100,000	7/227 (3%)	5/227 (2%)	1.4127 (0.4417, 4.5186) /0.560	0.8811 (-2.0690, 3.8311) /0.558	1.4000 (0.4510, 4.3461) /0.560	0.825
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Tonsillitis <100,000	6/227 (3%)	5/227 (2%)	1.2054 (0.3626, 4.0075) /0.761	0.4405 (-2.3879, 3.2690) /0.760	1.2000 (0.3715, 3.8760) /0.761	0.701
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<100,000	3/227 (1%)	8/227 (4%)	0.3666 (0.0960, 1.4000) /0.142	-2.2026 (-5.0241, 0.6188) /0.126	0.3750 (0.1008, 1.3955) /0.143	0.034
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<100,000	2/227 (<1%)	9/227 (4%)	0.2153 (0.0460, 1.0078) /0.051	-3.0837 (-5.8982, -0.2692) /0.032	0.2222 (0.0485, 1.0172) /0.053	0.536
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
<100,000	6/227 (3%)	5/227 (2%)	1.2054 (0.3626, 4.0075) /0.761	0.4405 (-2.3879, 3.2690) /0.760	1.2000 (0.3715, 3.8760) /0.761	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Conjunctivitis						
<100,000	7/227 (3%)	2/227 (<1%)	3.5795 (0.7355, 17.4206) /0.114	2.2026 (-0.3538, 4.7591) /0.091	3.5000 (0.7350, 16.6669) /0.116	0.100
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
<100,000	3/227 (1%)	5/227 (2%)	0.5946 (0.1404, 2.5182) /0.480	-0.8811 (-3.3002, 1.5381) /0.475	0.6000 (0.1451, 2.4810) /0.481	0.199
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<100,000	4/227 (2%)	4/227 (2%)	1.0000 (0.2470, 4.0482) />0.999	<0.0001 (-2.4205, 2.4205) />0.999	1.0000 (0.2532, 3.9497) />0.999	0.121
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes zoster						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.115
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
Tooth infection						
<100,000	6/227 (3%)	3/227 (1%)	2.0271 (0.5007, 8.2066) /0.322	1.3216 (-1.2400, 3.8832) /0.312	2.0000 (0.5064, 7.8994) /0.323	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	0.130
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
<100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.310
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis <100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
<100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	0.091
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum <100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.436
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Laryngitis <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.655
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.091
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis <100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	0.164
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.808
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Cystitis						
<100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ear infection						
<100,000	2/227 (<1%)	4/227 (2%)	0.4956 (0.0899, 2.7329) /0.420	-0.8811 (-2.9804, 1.2183) /0.411	0.5000 (0.0925, 2.7026) /0.421	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pharyngotons illitis						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.049
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.134
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Chlamydial infection <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.476
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.134
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
<100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.134
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Body tinea						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatitis A						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Secondary syphilis <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Tinea versicolour						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.409
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ureaplasma infection						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Epididymitis						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Proctitis chlamydial						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvovaginal candidiasis						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acute hepatitis B						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal abscess						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Balanitis candida						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chronic tonsillitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Mycoplasma infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Orchitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Otitis media						
<100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin infection <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tinea infection						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethritis chlamydial <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Abscess limb <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Angular cheilitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anorectal infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vulvovaginitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bronchitis pneumococcal						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cat scratch disease						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Conjunctivitis bacterial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dacryocystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Erysipelas						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Fungal infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis shigella						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gastrointestinal infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Genital infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary chlamydia infection						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genitourinary tract gonococcal infection						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gingivitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Helicobacter gastritis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Herpes virus infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Infectious colitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Lice infestation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphogranuloma venereum						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Malaria						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oophoritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Paronychia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pharyngeal chlamydia infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post procedural infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Pyelonephritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis chronic						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Respiratory tract infection bacterial						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Sexually transmitted disease						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Skin candida <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Staphylococcal abscess <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidi asis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tinea cruris						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Upper respiratory tract infection bacterial						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis mycoplasmal						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vaginal infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Viral tonsillitis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal mycotic infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvovaginitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<100,000	198/227 (87%)	20/227 (9%)	70.6655 (38.7016, 129.0286) /<.001	78.4141 (72.7173, 84.1109) /<.001	9.9000 (6.4953, 15.0894) /<.001	0.546
>=100,000	45/ 56 (80%)	6/ 56 (11%)	34.0909 (11.6566, 99.7019) /<.001	69.6429 (56.4557, 82.8300) /<.001	7.5000 (3.4827, 16.1510) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
<100,000	185/227 (81%)	0/227	>999 (>999, >999) /NC	NC	NC	NC
>=100,000	42/ 56 (75%)	0/ 56	>999 (>999, >999) /NC	73.7807 (45.0973, 102.4641) /<.001	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<100,000	38/227 (17%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	6/ 56 (11%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<100,000	32/227 (14%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	6/ 56 (11%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
<100,000	17/227 (7%)	3/227 (1%)	6.0444 (1.7461, 20.9235) /0.005	6.1674 (2.4349, 9.8999) /0.001	5.6667 (1.6839, 19.0699) /0.005	0.920
>=100,000	5/ 56 (9%)	1/ 56 (2%)	5.3922 (0.6092, 47.7282) /0.130	7.1429 (-1.0918, 15.3775) /0.089	5.0000 (0.6033, 41.4414) /0.136	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
<100,000	20/227 (9%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
<100,000	15/227 (7%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <100,000	6/227 (3%)	7/227 (3%)	0.8533 (0.2822, 2.5795) /0.779	-0.4405 (-3.5085, 2.6274) /0.778	0.8571 (0.2926, 2.5109) /0.779	0.918
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<100,000	6/227 (3%)	5/227 (2%)	1.2054 (0.3626, 4.0075) /0.761	0.4405 (-2.3879, 3.2690) /0.760	1.2000 (0.3715, 3.8760) /0.761	0.874
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Asthenia						
<100,000	12/227 (5%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Injection site erythema						
<100,000	13/227 (6%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<100,000	7/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Malaise						
<100,000	6/227 (3%)	1/227 (<1%)	6.1357 (0.7327, 51.3795) /0.094	2.2026 (-0.0550, 4.4603) /0.056	6.0000 (0.7282, 49.4396) /0.096	0.592
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
<100,000	5/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nodule						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chest pain						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site discolouration						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haemorrhage <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Catheter site erythema <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chills						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site cyst						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site granuloma <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site scar						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oedema peripheral						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Swelling <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Systemic inflammatory response syndrome <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vessel puncture site bruise						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	86/227 (38%)	55/227 (24%)	1.9074 (1.2721, 2.8600) /0.002	13.6564 (5.2367, 22.0761) /0.001	1.5636 (1.1770, 2.0772) /0.002	0.169
>=100,000	21/ 56 (38%)	20/ 56 (36%)	1.0800 (0.5005, 2.3304) /0.845	1.7857 (-16.0544, 19.6258) /0.844	1.0500 (0.6448, 1.7099) /0.845	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <100,000	25/227 (11%)	17/227 (7%)	1.5288 (0.8016, 2.9160) /0.198	3.5242 (-1.7964, 8.8449) /0.194	1.4706 (0.8168, 2.6477) /0.199	0.359
>=100,000	7/ 56 (13%)	8/ 56 (14%)	0.8571 (0.2883, 2.5485) /0.782	-1.7857 (-14.3962, 10.8248) /0.781	0.8750 (0.3403, 2.2497) /0.782	
Nausea <100,000	14/227 (6%)	7/227 (3%)	2.0657 (0.8178, 5.2181) /0.125	3.0837 (-0.7700, 6.9374) /0.117	2.0000 (0.8226, 4.8626) /0.126	0.134
>=100,000	2/ 56 (4%)	4/ 56 (7%)	0.4815 (0.0845, 2.7420) /0.410	-3.5714 (-11.8854, 4.7426) /0.400	0.5000 (0.0954, 2.6204) /0.412	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
<100,000	12/227 (5%)	4/227 (2%)	3.1116 (0.9882, 9.7976) /0.052	3.5242 (0.1475, 6.9010) /0.041	3.0000 (0.9822, 9.1627) /0.054	0.002
>=100,000	0/ 56	4/ 56 (7%)	<0.0001 (<0.0001, -) />0.999	-9.2175 (-36.7480, 18.3129) /0.512	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <100,000	16/227 (7%)	2/227 (<1%)	8.5308 (1.9382, 37.5475) /0.005	6.1674 (2.6227, 9.7121) /<.001	8.0000 (1.8608, 34.3931) /0.005	0.044
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Toothache <100,000	7/227 (3%)	5/227 (2%)	1.4127 (0.4417, 4.5186) /0.560	0.8811 (-2.0690, 3.8311) /0.558	1.4000 (0.4510, 4.3461) /0.560	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <100,000	7/227 (3%)	3/227 (1%)	2.3758 (0.6066, 9.3050) /0.214	1.7621 (-0.9332, 4.4574) /0.200	2.3333 (0.6110, 8.9105) /0.215	0.411
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Constipation <100,000	7/227 (3%)	1/227 (<1%)	7.1909 (0.8775, 58.9279) /0.066	2.6432 (0.2349, 5.0514) /0.031	7.0000 (0.8682, 56.4359) /0.068	0.012
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <100,000	6/227 (3%)	3/227 (1%)	2.0271 (0.5007, 8.2066) /0.322	1.3216 (-1.2400, 3.8832) /0.312	2.0000 (0.5064, 7.8994) /0.323	0.382
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis <100,000	5/227 (2%)	2/227 (<1%)	2.5338 (0.4865, 13.1970) /0.270	1.3216 (-0.9419, 3.5850) /0.252	2.5000 (0.4901, 12.7529) /0.270	0.280
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	0.084
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.808
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Anogenital dysplasia <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.339
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
<100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	0.206
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Food poisoning						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
Odynophagia						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.206
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.708
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.187
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Abdominal pain lower <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Haemorrhoidal haemorrhage						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal distension <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal inflammation						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Diarrhoea haemorrhagic						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dry mouth <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Faeces soft <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroduodenitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gingival bleeding						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	
Lip dry						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Stomatitis						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aerophagia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal fistula <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal ulcer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Barrett's oesophagus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile acid malabsorption						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bowel movement irregularity						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis microscopic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysbacteriosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Enteritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterocolitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Epigastric discomfort						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal sounds abnormal						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gingival pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival swelling						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haematochezi ^a						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Large intestine perforation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lymphoid hyperplasia of intestine						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal polyp						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oral pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Palatal ulcer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pancreatitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Paraesthesia oral						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rectal discharge						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal fissure						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Tongue eruption						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth development disorder						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Umbilical hernia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	52/227 (23%)	34/227 (15%)	1.6867 (1.0456, 2.7211) /0.032	7.9295 (0.7576, 15.1014) /0.030	1.5294 (1.0343, 2.2615) /0.033	0.577
>=100,000	12/ 56 (21%)	10/ 56 (18%)	1.2545 (0.4923, 3.1971) /0.635	3.5714 (-11.1295, 18.2723) /0.634	1.2000 (0.5651, 2.5481) /0.635	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)	
Back pain	<100,000	19/227 (8%)	12/227 (5%)	1.6366 (0.7751, 3.4558) /0.196	3.0837 (-1.5479, 7.7153) /0.192	1.5833 (0.7871, 3.1849) /0.198	0.577
	>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	
Myalgia	<100,000	11/227 (5%)	4/227 (2%)	2.8391 (0.8904, 9.0527) /0.078	3.0837 (-0.1923, 6.3597) /0.065	2.7500 (0.8888, 8.5087) /0.079	0.945
	>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <100,000	5/227 (2%)	6/227 (3%)	0.8296 (0.2495, 2.7580) /0.761	-0.4405 (-3.2690, 2.3879) /0.760	0.8333 (0.2580, 2.6916) /0.761	0.176
>=100,000	4/ 56 (7%)	1/ 56 (2%)	4.2308 (0.4577, 39.1046) /0.204	5.3571 (-2.2277, 12.9419) /0.166	4.0000 (0.4614, 34.6768) /0.208	
Muscle contracture <100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
<100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Musculoskeletal chest pain						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.542
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.339
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
<100,000	5/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.708
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Osteochondro- sis <100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Musculoskeletal discomfort <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Osteoarthritis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Plantar fasciitis						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Spinal disorder						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Arthritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bursitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Groin pain						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Joint swelling						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Osteoporosis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Soft tissue mass						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tendon pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<100,000	55/227 (24%)	25/227 (11%)	2.5837 (1.5443, 4.3227) /<.001	13.2159 (6.3128, 20.1189) /<.001	2.2000 (1.4233, 3.4006) /<.001	0.185
>=100,000	9/ 56 (16%)	8/ 56 (14%)	1.1489 (0.4086, 3.2305) /0.792	1.7857 (-11.5005, 15.0720) /0.792	1.1250 (0.4678, 2.7052) /0.792	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
<100,000	32/227 (14%)	15/227 (7%)	2.3193 (1.2188, 4.4135) /0.010	7.4890 (1.9269, 13.0510) /0.008	2.1333 (1.1884, 3.8296) /0.011	0.320
>=100,000	7/ 56 (13%)	6/ 56 (11%)	1.1905 (0.3734, 3.7953) /0.768	1.7857 (-10.0739, 13.6454) /0.768	1.1667 (0.4184, 3.2535) /0.768	
Dizziness						
<100,000	13/227 (6%)	2/227 (<1%)	6.8341 (1.5243, 30.6411) /0.012	4.8458 (1.5879, 8.1038) /0.004	6.5000 (1.4837, 28.4768) /0.013	0.427
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.134
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Migraine <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Syncope <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Disturbance in attention <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Lethargy <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Poor quality sleep <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Somnolence <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anosmia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Autonomic nervous system imbalance						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical neuritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypoaesthesia						
^a <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intercostal neuralgia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nerve compression						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Radiculitis brachial						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tremor						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Trigeminal neuralgia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Visual field defect						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<100,000	37/227 (16%)	24/227 (11%)	1.6471 (0.9499, 2.8563) /0.076	5.7269 (-0.5251, 11.9789) /0.073	1.5417 (0.9543, 2.4905) /0.077	0.675
>=100,000	10/ 56 (18%)	8/ 56 (14%)	1.3043 (0.4732, 3.5950) /0.607	3.5714 (-10.0160, 17.1589) /0.606	1.2500 (0.5328, 2.9325) /0.608	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
<100,000	5/227 (2%)	5/227 (2%)	1.0000 (0.2855, 3.5025) />0.999	<0.0001 (-2.7001, 2.7001) />0.999	1.0000 (0.2935, 3.4071) />0.999	0.376
>=100,000	1/ 56 (2%)	3/ 56 (5%)	0.3212 (0.0324, 3.1859) /0.332	-3.5714 (-10.4133, 3.2704) /0.306	0.3333 (0.0357, 3.1082) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema						
<100,000	5/227 (2%)	4/227 (2%)	1.2556 (0.3328, 4.7374) /0.737	0.4405 (-2.1236, 3.0047) /0.736	1.2500 (0.3400, 4.5951) /0.737	0.851
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	
Acne						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.134
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dermatitis						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Erythema						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperhidrosi s						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dermal cyst <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dyshidrotic eczema						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Night sweats <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Papule						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pityriasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rash pruritic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin mass						
<100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urticaria						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Alopecia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood blister						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dandruff						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis allergic						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ephelides						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Lipodystrophy acquired						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail pigmentation						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Penile ulceration						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pityriasis alba						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pruritus						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Purpura <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash macular						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash morbilliform						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rosacea <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin erosion						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hyperpigmentation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin hypopigmentation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin induration						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin reaction						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xeroderma <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<100,000	37/227 (16%)	27/227 (12%)	1.4425 (0.8454, 2.4614) /0.179	4.4053 (-1.9839, 10.7945) /0.177	1.3704 (0.8645, 2.1723) /0.180	0.412
>=100,000	6/ 56 (11%)	7/ 56 (13%)	0.8400 (0.2635, 2.6780) /0.768	-1.7857 (-13.6454, 10.0739) /0.768	0.8571 (0.3074, 2.3903) /0.768	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
<100,000	10/227 (4%)	9/227 (4%)	1.1162 (0.4449, 2.8008) /0.815	0.4405 (-3.2432, 4.1243) /0.815	1.1111 (0.4602, 2.6829) /0.815	0.043
>=100,000	0/ 56	3/ 56 (5%)	<0.0001 (<0.0001, -) />0.999	-7.5123 (-34.9111, 19.8865) /0.591	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<100,000	11/227 (5%)	3/227 (1%)	3.8025 (1.0465, 13.8165) /0.042	3.5242 (0.3604, 6.6881) /0.029	3.6667 (1.0367, 12.9690) /0.044	0.408
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
<100,000	8/227 (4%)	1/227 (<1%)	8.2557 (1.0240, 66.5565) /0.047	3.0837 (0.5350, 5.6324) /0.018	8.0000 (1.0088, 63.4428) /0.049	0.515
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Catarrh						
<100,000	5/227 (2%)	4/227 (2%)	1.2556 (0.3328, 4.7374) /0.737	0.4405 (-2.1236, 3.0047) /0.736	1.2500 (0.3400, 4.5951) /0.737	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
<100,000	1/227 (<1%)	4/227 (2%)	0.2467 (0.0274, 2.2243) /0.212	-1.3216 (-3.2377, 0.5946) /0.176	0.2500 (0.0282, 2.2195) /0.213	0.436
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea <100,000	0/227	4/227 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Asthma <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.050
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Productive cough						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Sinus congestion						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchial obstruction						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchitis chronic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nasal dryness <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal obstruction						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nasal turbinate hypertrophy						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Reflux laryngitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Throat irritation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tonsillar hypertrophy						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Wheezing						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
<100,000	25/227 (11%)	31/227 (14%)	0.7825 (0.4459, 1.3731) /0.393	-2.6432 (-8.6879, 3.4016) /0.391	0.8065 (0.4922, 1.3213) /0.393	0.721
>=100,000	6/ 56 (11%)	6/ 56 (11%)	1.0000 (0.3019, 3.3120) />0.999	<0.0001 (-11.4562, 11.4562) />0.999	1.0000 (0.3433, 2.9132) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
<100,000	2/227 (<1%)	5/227 (2%)	0.3947 (0.0758, 2.0556) /0.270	-1.3216 (-3.5850, 0.9419) /0.252	0.4000 (0.0784, 2.0405) /0.270	0.880
>=100,000	1/ 56 (2%)	2/ 56 (4%)	0.4909 (0.0432, 5.5742) /0.566	-1.7857 (-7.7569, 4.1855) /0.558	0.5000 (0.0467, 5.3578) /0.567	
Contusion						
<100,000	7/227 (3%)	2/227 (<1%)	3.5795 (0.7355, 17.4206) /0.114	2.2026 (-0.3538, 4.7591) /0.091	3.5000 (0.7350, 16.6669) /0.116	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.198
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Arthropod sting <100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.305
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Ankle fracture <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ligament sprain						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Meniscus injury <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle strain						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Procedural pain <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Wound						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Cranio-cerebral injury						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Exposure via inhalation						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fracture						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Heat stroke						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Joint dislocation <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Neck injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile contusion						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post lumbar puncture syndrome						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rib fracture <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Skin injury						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Spinal column injury						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tendon injury						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tibia fracture						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Traumatic haematoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral injury						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	33/227 (15%)	23/227 (10%)	1.5087 (0.8554, 2.6612) /0.155	4.4053 (-1.6308, 10.4413) /0.153	1.4348 (0.8706, 2.3646) /0.157	0.596
>=100,000	8/ 56 (14%)	4/ 56 (7%)	2.1667 (0.6129, 7.6592) /0.230	7.1429 (-4.2367, 18.5225) /0.219	2.0000 (0.6386, 6.2638) /0.234	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<100,000	8/227 (4%)	5/227 (2%)	1.6219 (0.5224, 5.0352) /0.403	1.3216 (-1.7442, 4.3874) /0.398	1.6000 (0.5315, 4.8168) /0.403	0.756
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	0.061
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <100,000	2/227 (<1%)	4/227 (2%)	0.4956 (0.0899, 2.7329) /0.420	-0.8811 (-2.9804, 1.2183) /0.411	0.5000 (0.0925, 2.7026) /0.421	0.164
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Alanine aminotransferase increased						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
<100,000	0/227	3/227 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.050
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood glucose abnormal						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Aortic bruit						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blood creatinine increased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood folate decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blood triglycerides increased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Electrocardiogram QT prolonged						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Haemoglobin decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heart rate increased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatic enzyme increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Mycoplasma test positive						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Platelet count decreased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Protein urine present						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Total lung capacity decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Treponema test positive						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Weight increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<100,000	34/227 (15%)	23/227 (10%)	1.5625 (0.8885, 2.7480) /0.121	4.8458 (-1.2336, 10.9252) /0.118	1.4783 (0.9001, 2.4279) /0.123	0.592
>=100,000	4/ 56 (7%)	4/ 56 (7%)	1.0000 (0.2373, 4.2132) />0.999	<0.0001 (-9.5392, 9.5392) />0.999	1.0000 (0.2630, 3.8019) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety <100,000	11/227 (5%)	4/227 (2%)	2.8391 (0.8904, 9.0527) /0.078	3.0837 (-0.1923, 6.3597) /0.065	2.7500 (0.8888, 8.5087) /0.079	0.377
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	
<hr/>						
Insomnia <100,000	6/227 (3%)	4/227 (2%)	1.5136 (0.4214, 5.4370) /0.525	0.8811 (-1.8179, 3.5800) /0.522	1.5000 (0.4290, 5.2444) /0.525	0.326
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <100,000	5/227 (2%)	4/227 (2%)	1.2556 (0.3328, 4.7374) /0.737	0.4405 (-2.1236, 3.0047) /0.736	1.2500 (0.3400, 4.5951) /0.737	0.294
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abnormal dreams <100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.525
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
<100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Libido decreased						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Panic attack						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nervousness						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Stress <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal ideation						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acute stress disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Affective disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Drug abuse						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Major depression <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paranoia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Suicide attempt <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<100,000	25/227 (11%)	18/227 (8%)	1.4370 (0.7608, 2.7143) /0.264	3.0837 (-2.2959, 8.4633) /0.261	1.3889 (0.7798, 2.4738) /0.265	0.817
>=100,000	8/ 56 (14%)	5/ 56 (9%)	1.7000 (0.5199, 5.5592) /0.380	5.3571 (-6.4656, 17.1798) /0.374	1.6000 (0.5576, 4.5914) /0.382	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<100,000	17/227 (7%)	11/227 (5%)	1.5896 (0.7273, 3.4741) /0.245	2.6432 (-1.7758, 7.0621) /0.241	1.5455 (0.7405, 3.2255) /0.246	0.434
>=100,000	6/ 56 (11%)	2/ 56 (4%)	3.2400 (0.6248, 16.8013) /0.162	7.1429 (-2.3042, 16.5899) /0.138	3.0000 (0.6324, 14.2315) /0.167	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
<100,000	0/227	3/227 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Hypovitaminosis						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypercholesterolaemia						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Type 2 diabetes mellitus						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.050
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasae mia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertriglyceridaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Diabetes mellitus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Glucose tolerance impaired						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gout						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypocalcaemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypomagnesaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Iron deficiency						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	18/227 (8%)	17/227 (7%)	1.0639 (0.5336, 2.1210) /0.860	0.4405 (-4.4665, 5.3476) /0.860	1.0588 (0.5601, 2.0017) /0.860	0.308
>=100,000	5/ 56 (9%)	2/ 56 (4%)	2.6471 (0.4914, 14.2583) /0.257	5.3571 (-3.5537, 14.2680) /0.239	2.5000 (0.5060, 12.3509) /0.261	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<100,000	8/227 (4%)	4/227 (2%)	2.0365 (0.6045, 6.8611) /0.251	1.7621 (-1.1846, 4.7088) /0.241	2.0000 (0.6109, 6.5482) /0.252	>0.999
>=100,000	4/ 56 (7%)	2/ 56 (4%)	2.0769 (0.3647, 11.8279) /0.410	3.5714 (-4.7426, 11.8854) /0.400	2.0000 (0.3816, 10.4815) /0.412	
Skin papilloma						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipoma <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Melanocytic naevus						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oral papilloma						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Uterine leiomyoma						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Adenocarcinoma of colon						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal neoplasm						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Benign spleen tumour						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dysplastic naevus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Kidney angiomyolipoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasm skin						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oral fibroma						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin cancer <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<100,000	13/227 (6%)	16/227 (7%)	0.8011 (0.3761, 1.7064) /0.565	-1.3216 (-5.8187, 3.1755) /0.565	0.8125 (0.4001, 1.6499) /0.566	0.110
>=100,000	6/ 56 (11%)	2/ 56 (4%)	3.2400 (0.6248, 16.8013) /0.162	7.1429 (-2.3042, 16.5899) /0.138	3.0000 (0.6324, 14.2315) /0.167	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
<100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	0.242
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Erectile dysfunction						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.525
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Prostatitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genital lesion						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Breast pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dysfunctional uterine bleeding						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoea ^a						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Menopausal symptoms						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ovarian cyst						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Polymenorrhoea						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Testicular pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vaginal dysplasia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal haemorrhage						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vaginal ulceration						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvar dysplasia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal pruritus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<100,000	12/227 (5%)	8/227 (4%)	1.5279 (0.6125, 3.8117) /0.363	1.7621 (-2.0097, 5.5340) /0.360	1.5000 (0.6250, 3.6000) /0.364	0.657
>=100,000	3/ 56 (5%)	3/ 56 (5%)	1.0000 (0.1930, 5.1809) />0.999	<0.0001 (-8.3403, 8.3403) />0.999	1.0000 (0.2108, 4.7438) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
<100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.774
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	0.339
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.708
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Iron deficiency anaemia <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypochromic anaemia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Normocytic anaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splenomegaly <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<100,000	12/227 (5%)	4/227 (2%)	3.1116 (0.9882, 9.7976) /0.052	3.5242 (0.1475, 6.9010) /0.041	3.0000 (0.9822, 9.1627) /0.054	0.010
>=100,000	1/ 56 (2%)	5/ 56 (9%)	0.1855 (0.0210, 1.6415) /0.130	-7.1429 (-15.3775, 1.0918) /0.089	0.2000 (0.0241, 1.6577) /0.136	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dysuria						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	0.084
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Proteinuria						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal failure						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Calculus urinary						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glomerulonephritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Micturition urgency						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nephropathy						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urethral caruncle <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral discharge						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Urethral pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary incontinence						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<100,000	9/227 (4%)	8/227 (4%)	1.1302 (0.4281, 2.9833) /0.805	0.4405 (-3.0519, 3.9330) /0.805	1.1250 (0.4419, 2.8640) /0.805	0.062
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Asthenopia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Astigmatism						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blepharospasm						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chalazion <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chorioretinal disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Conjunctivitis allergic						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic retinopathy						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dry eye						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Eye irritation <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Eye pruritus <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Glare						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Glaucoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Meibomian gland dysfunction						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Uveitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<100,000	9/227 (4%)	3/227 (1%)	3.0826 (0.8236, 11.5380) /0.095	2.6432 (-0.2980, 5.5843) /0.078	3.0000 (0.8228, 10.9380) /0.096	0.070
>=100,000	1/ 56 (2%)	3/ 56 (5%)	0.3212 (0.0324, 3.1859) /0.332	-3.5714 (-10.4133, 3.2704) /0.306	0.3333 (0.0357, 3.1082) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.542
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vertigo positional						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Deafness						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective myringitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tinnitus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<100,000	6/227 (3%)	3/227 (1%)	2.0271 (0.5007, 8.2066) /0.322	1.3216 (-1.2400, 3.8832) /0.312	2.0000 (0.5064, 7.8994) /0.323	0.585
>=100,000	4/ 56 (7%)	1/ 56 (2%)	4.2308 (0.4577, 39.1046) /0.204	5.3571 (-2.2277, 12.9419) /0.166	4.0000 (0.4614, 34.6768) /0.208	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertension <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.542
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	
Circulatory collapse <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperaemia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Intermittent claudication						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Peripheral ischaemia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral venous disease						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Thrombophlebitis superficial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<100,000	8/227 (4%)	2/227 (<1%)	4.1096 (0.8630, 19.5689) /0.076	2.6432 (-0.0460, 5.3323) /0.054	4.0000 (0.8588, 18.6309) /0.077	0.637
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.389
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypersensitivity						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Mite allergy <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	0.562
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperbilirubinaemia						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bile duct stone						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Cholelithiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatic steatosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis toxic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hydrocholecystis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Atrioventricular block first degree						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Goitre						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypothyroidism						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Keratitis follicular						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth extraction						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	44/143 (31%)	62/145 (43%)	0.5950 (0.3667, 0.9655) /0.036	-11.9894 (-23.0378, -0.9410) /0.033	0.7196 (0.5280, 0.9808) /0.037	0.198
35-<50	38/107 (36%)	51/109 (47%)	0.6263 (0.3627, 1.0814) /0.093	-11.2750 (-24.3120, 1.7620) /0.090	0.7590 (0.5487, 1.0499) /0.096	
>=50	11/ 33 (33%)	6/ 29 (21%)	1.9167 (0.6046, 6.0758) /0.269	12.6437 (-9.1748, 34.4621) /0.256	1.6111 (0.6814, 3.8095) /0.277	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	69/143 (48%)	66/145 (46%)	1.1161 (0.7024, 1.7734) /0.642	2.7345 (-8.7883, 14.2574) /0.642	1.0601 (0.8289, 1.3557) /0.642	0.908
35-<50	49/107 (46%)	47/109 (43%)	1.1145 (0.6514, 1.9066) /0.692	2.6751 (-10.5747, 15.9249) /0.692	1.0620 (0.7881, 1.4312) /0.692	
>=50	14/ 33 (42%)	10/ 29 (34%)	1.4000 (0.4993, 3.9253) /0.522	7.9415 (-16.2164, 32.0994) /0.519	1.2303 (0.6487, 2.3334) /0.526	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<35	24/143 (17%)	20/145 (14%)	1.2605 (0.6618, 2.4009) /0.481	2.9901 (-5.3177, 11.2979) /0.481	1.2168 (0.7044, 2.1018) /0.482	0.859
35-<50	20/107 (19%)	18/109 (17%)	1.1622 (0.5764, 2.3435) /0.674	2.1778 (-7.9785, 12.3341) /0.674	1.1319 (0.6349, 2.0180) /0.675	
>=50	6/ 33 (18%)	6/ 29 (21%)	0.8519 (0.2414, 3.0057) /0.803	-2.5078 (-22.2697, 17.2540) /0.804	0.8788 (0.3183, 2.4266) /0.803	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection <35	15/143 (10%)	13/145 (9%)	1.1899 (0.5447, 2.5996) /0.663	1.5240 (-5.3204, 8.3684) /0.663	1.1700 (0.5776, 2.3699) /0.663	0.508
35-<50	14/107 (13%)	7/109 (6%)	2.1935 (0.8485, 5.6708) /0.105	6.6621 (-1.2124, 14.5366) /0.097	2.0374 (0.8560, 4.8494) /0.108	
>=50	3/ 33 (9%)	3/ 29 (10%)	0.8667 (0.1608, 4.6701) /0.868	-1.2539 (-16.0546, 13.5468) /0.868	0.8788 (0.1921, 4.0203) /0.868	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Influenza <35	13/143 (9%)	11/145 (8%)	1.2182 (0.5267, 2.8173) /0.645	1.5047 (-4.8808, 7.8902) /0.644	1.1983 (0.5554, 2.5856) /0.645	0.871
35-<50	4/107 (4%)	5/109 (5%)	0.8078 (0.2109, 3.0933) /0.755	-0.8488 (-6.1728, 4.4751) /0.755	0.8150 (0.2249, 2.9530) /0.755	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	9/143 (6%)	4/145 (3%)	2.3675 (0.7122, 7.8707) /0.160	3.5351 (-1.2555, 8.3257) /0.148	2.2815 (0.7189, 7.2408) /0.162	0.240
35-<50	4/107 (4%)	4/109 (4%)	1.0194 (0.2483, 4.1851) /0.979	0.0686 (-4.9691, 5.1062) /0.979	1.0187 (0.2615, 3.9690) /0.979	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pharyngitis <35	9/143 (6%)	4/145 (3%)	2.3675 (0.7122, 7.8707) /0.160	3.5351 (-1.2555, 8.3257) /0.148	2.2815 (0.7189, 7.2408) /0.162	0.213
35-<50	3/107 (3%)	5/109 (5%)	0.6000 (0.1398, 2.5757) /0.492	-1.7834 (-6.8042, 3.2374) /0.486	0.6112 (0.1498, 2.4942) /0.493	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<35	7/143 (5%)	3/145 (2%)	2.4363 (0.6173, 9.6144) /0.204	2.8261 (-1.4016, 7.0539) /0.190	2.3660 (0.6241, 8.9694) /0.205	0.657
35-<50	3/107 (3%)	3/109 (3%)	1.0192 (0.2011, 5.1658) /0.982	0.0514 (-4.3322, 4.4351) /0.982	1.0187 (0.2103, 4.9354) /0.982	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis <35	5/143 (3%)	3/145 (2%)	1.7150 (0.4021, 7.3141) /0.466	1.4275 (-2.3714, 5.2265) /0.461	1.6900 (0.4115, 6.9400) /0.467	0.335
35-<50	4/107 (4%)	5/109 (5%)	0.8078 (0.2109, 3.0933) /0.755	-0.8488 (-6.1728, 4.4751) /0.755	0.8150 (0.2249, 2.9530) /0.755	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.576
35-<50	5/107 (5%)	4/109 (4%)	1.2868 (0.3360, 4.9276) /0.713	1.0032 (-4.3308, 6.3371) /0.712	1.2734 (0.3514, 4.6140) /0.713	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.168
35-<50	4/107 (4%)	4/109 (4%)	1.0194 (0.2483, 4.1851) /0.979	0.0686 (-4.9691, 5.1062) /0.979	1.0187 (0.2615, 3.9690) /0.979	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis <35	7/143 (5%)	4/145 (3%)	1.8143 (0.5194, 6.3381) /0.351	2.1365 (-2.2922, 6.5651) /0.344	1.7745 (0.5310, 5.9302) /0.352	0.937
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	0.116
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	3/ 29 (10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis <35	3/143 (2%)	4/145 (3%)	0.7554 (0.1660, 3.4368) /0.717	-0.6607 (-4.2138, 2.8923) /0.716	0.7605 (0.1733, 3.3375) /0.717	0.235
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Gonorrhoea <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.784
35-<50	3/107 (3%)	4/109 (4%)	0.7572 (0.1654, 3.4667) /0.720	-0.8660 (-5.5821, 3.8502) /0.719	0.7640 (0.1751, 3.3329) /0.720	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	>0.999
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Herpes simplex <35	1/143 (<1%)	3/145 (2%)	0.3333 (0.0343, 3.2429) /0.344	-1.3697 (-4.0591, 1.3198) /0.318	0.3380 (0.0356, 3.2112) /0.345	0.333
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.220
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <35	2/143 (1%)	5/145 (3%)	0.3972 (0.0758, 2.0813) /0.275	-2.0497 (-5.5887, 1.4894) /0.256	0.4056 (0.0800, 2.0566) /0.276	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<35	4/143 (3%)	2/145 (1%)	2.0576 (0.3709, 11.4144) /0.409	1.4179 (-1.8848, 4.7206) /0.400	2.0280 (0.3774, 10.8985) /0.410	0.917
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	0.289
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection <35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	0.059
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	0.495
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	3/ 29 (10%)	0.2708 (0.0266, 2.7603) /0.270	-7.3145 (-19.8470, 5.2179) /0.253	0.2929 (0.0322, 2.6636) /0.276	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hordeolum <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.740
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Laryngitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.448
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	>0.999
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sinusitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Infection <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
<35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea versicolour						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chlamydial infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Helicobacter infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Viral pharyngitis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanitis candida						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chronic tonsillitis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Epididymitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Mycoplasma infection						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Otitis externa						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal candidiasis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Acarodermatitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal abscess						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vulvovaginitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis pneumococcal <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cat scratch disease						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Conjunctivitis bacterial						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dacryocystitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Fungal infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Gastroenteritis shigella						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Genital infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Groin abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter gastritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Impetigo						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infectious colitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Lice infestation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Oophoritis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Otitis media <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Pertussis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis chronic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection bacterial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal abscess						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Strongyloidiasis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea cruris <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tonsillitis bacterial <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection bacterial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Viral tonsillitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	61/143 (43%)	11/145 (8%)	9.0621 (4.5075, 18.2190) /<.001	35.0711 (25.8905, 44.2517) /<.001	5.6230 (3.0890, 10.2359) /<.001	NC
35-<50	56/107 (52%)	7/109 (6%)	16.0000 (6.8072, 37.6074) /<.001	45.9144 (35.3913, 56.4376) /<.001	8.1495 (3.8919, 17.0651) /<.001	
>=50	19/ 33 (58%)	3/ 29 (10%)	11.7619 (2.9586, 46.7593) /<.001	47.2309 (27.0519, 67.4100) /<.001	5.5657 (1.8328, 16.9011) /0.002	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	60/143 (42%)	0/145	>999 (>999, >999) /NC	42.3495 (24.1651, 60.5340) /<.001	>999 (>999, >999) /NC	NC
35-<50	51/107 (48%)	0/109	>999 (>999, >999) /NC	47.7770 (26.7528, 68.8013) /<.001	>999 (>999, >999) /NC	
>=50	13/ 33 (39%)	0/ 29	>999 (>999, >999) /NC	39.9104 (-0.1523, 79.9731) /0.051	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site nodule						
<35	21/143 (15%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	14/107 (13%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	4/ 33 (12%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration <35	13/143 (9%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	11/107 (10%)	0/109	>999 (>999, >999) /NC	12.2081 (-7.7158, 32.1319) /0.230	>999 (>999, >999) /NC	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site swelling <35	11/143 (8%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	3/ 33 (9%)	0/ 29	>999 (>999, >999) /NC	11.0748 (-27.1430, 49.2927) /0.570	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	8/143 (6%)	2/145 (1%)	4.2370 (0.8839, 20.3096) /0.071	4.2151 (-0.0029, 8.4331) /0.050	4.0559 (0.8763, 18.7718) /0.073	NC
35-<50	6/107 (6%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus <35	5/143 (3%)	0/145	>999 (>999, >999) /NC	5.7283 (-11.2366, 22.6932) /0.508	>999 (>999, >999) /NC	NC
35-<50	6/107 (6%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness <35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.836
35-<50	2/107 (2%)	3/109 (3%)	0.6730 (0.1102, 4.1101) /0.668	-0.8831 (-4.8854, 3.1191) /0.665	0.6791 (0.1158, 3.9839) /0.668	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	2/143 (1%)	4/145 (3%)	0.5000 (0.0901, 2.7738) /0.428	-1.3600 (-4.6481, 1.9280) /0.418	0.5070 (0.0943, 2.7246) /0.429	0.653
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.146
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	4/ 33 (12%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site erythema						
<35	6/143 (4%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site haemorrhage						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
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 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chest pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Injection site anaesthesia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cyst <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site granuloma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Injection site scar						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Oedema peripheral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Swelling						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site bruise						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	39/143 (27%)	32/145 (22%)	1.3242 (0.7732, 2.2679) /0.306	5.2038 (-4.7384, 15.1459) /0.305	1.2358 (0.8231, 1.8555) /0.307	0.886
35-<50	26/107 (24%)	25/109 (23%)	1.0785 (0.5755, 2.0213) /0.814	1.3633 (-9.9651, 12.6917) /0.814	1.0594 (0.6557, 1.7119) /0.814	
>=50	7/ 33 (21%)	5/ 29 (17%)	1.2923 (0.3612, 4.6234) /0.693	3.9707 (-15.6139, 23.5554) /0.691	1.2303 (0.4377, 3.4584) /0.694	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	7/143 (5%)	13/145 (9%)	0.5226 (0.2022, 1.3507) /0.180	-4.0704 (-9.9124, 1.7716) /0.172	0.5460 (0.2244, 1.3287) /0.182	0.166
35-<50	11/107 (10%)	6/109 (6%)	1.9670 (0.7002, 5.5255) /0.199	4.7758 (-2.3968, 11.9483) /0.192	1.8676 (0.7163, 4.8693) /0.201	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Nausea <35	10/143 (7%)	5/145 (3%)	2.1053 (0.7012, 6.3210) /0.184	3.5447 (-1.5829, 8.6723) /0.175	2.0280 (0.7108, 5.7858) /0.186	0.811
35-<50	4/107 (4%)	3/109 (3%)	1.3722 (0.2997, 6.2821) /0.684	0.9860 (-3.7418, 5.7138) /0.683	1.3583 (0.3114, 5.9251) /0.684	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abdominal pain						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.121
35-<50	3/107 (3%)	6/109 (6%)	0.4952 (0.1206, 2.0332) /0.329	-2.7008 (-8.0032, 2.6015) /0.318	0.5093 (0.1307, 1.9845) /0.331	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <35	8/143 (6%)	1/145 (<1%)	8.5333 (1.0533, 69.1345) /0.045	4.9048 (0.9045, 8.9050) /0.016	8.1119 (1.0277, 64.0275) /0.047	0.794
35-<50	4/107 (4%)	1/109 (<1%)	4.1942 (0.4611, 38.1515) /0.203	2.8209 (-1.1945, 6.8362) /0.169	4.0748 (0.4629, 35.8673) /0.206	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.512
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache <35	4/143 (3%)	2/145 (1%)	2.0576 (0.3709, 11.4144) /0.409	1.4179 (-1.8848, 4.7206) /0.400	2.0280 (0.3774, 10.8985) /0.410	>0.999
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <35	5/143 (3%)	1/145 (<1%)	5.2174 (0.6019, 45.2267) /0.134	2.8068 (-0.4915, 6.1052) /0.095	5.0699 (0.5997, 42.8582) /0.136	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.078
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Constipation <35	1/143 (<1%)	3/145 (2%)	0.3333 (0.0343, 3.2429) /0.344	-1.3697 (-4.0591, 1.3198) /0.318	0.3380 (0.0356, 3.2112) /0.345	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	>0.999
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.711
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning <35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dry mouth <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroduodentis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival bleeding						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stomatitis <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Abdominal distension <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Aerophagia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal fistula <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal inflammation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal pruritus						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anal ulcer <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Aphthous ulcer <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bile acid malabsorption						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bowel movement irregularity <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis microscopic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dysbacteriosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Enteritis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enterocolitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Faeces soft						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal sounds abnormal						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Gingival swelling <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Inguinal hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal polyp <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Oral pain <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palatal ulcer <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rectal discharge <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<35	22/143 (15%)	9/145 (6%)	2.7475 (1.2182, 6.1964) /0.015	9.1777 (2.0789, 16.2765) /0.011	2.4786 (1.1822, 5.1968) /0.016	0.006
35-<50	19/107 (18%)	14/109 (13%)	1.4651 (0.6929, 3.0978) /0.317	4.9130 (-4.6725, 14.4985) /0.315	1.3825 (0.7314, 2.6133) /0.319	
>=50	5/ 33 (15%)	11/ 29 (38%)	0.2922 (0.0870, 0.9815) /0.047	-22.7795 (-44.2625, -1.2966) /0.038	0.3994 (0.1573, 1.0144) /0.054	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Back pain <35	7/143 (5%)	2/145 (1%)	3.6801 (0.7513, 18.0266) /0.108	3.5158 (-0.4979, 7.5295) /0.086	3.5490 (0.7500, 16.7945) /0.110	0.139
35-<50	6/107 (6%)	3/109 (3%)	2.0990 (0.5112, 8.6185) /0.304	2.8552 (-2.4773, 8.1877) /0.294	2.0374 (0.5229, 7.9380) /0.305	
>=50	2/ 33 (6%)	4/ 29 (14%)	0.4032 (0.0682, 2.3845) /0.317	-7.7325 (-22.6919, 7.2269) /0.311	0.4394 (0.0867, 2.2257) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia <35	6/143 (4%)	2/145 (1%)	3.1314 (0.6213, 15.7814) /0.167	2.8165 (-0.9785, 6.6115) /0.146	3.0420 (0.6244, 14.8210) /0.169	0.607
35-<50	5/107 (5%)	1/109 (<1%)	5.2941 (0.6081, 46.0909) /0.131	3.7555 (-0.6259, 8.1368) /0.093	5.0935 (0.6051, 42.8779) /0.134	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.209
35-<50	1/107 (<1%)	4/109 (4%)	0.2476 (0.0272, 2.2526) /0.215	-2.7351 (-6.7079, 1.2376) /0.177	0.2547 (0.0289, 2.2417) /0.218	
>=50	3/ 33 (9%)	1/ 29 (3%)	2.8000 (0.2749, 28.5213) /0.385	5.6426 (-6.2025, 17.4878) /0.350	2.6364 (0.2899, 23.9723) /0.389	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms <35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tendonitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteochondros is						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Spinal disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Groin pain <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Intervertebra l disc disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Osteoarthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Soft tissue mass <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	26/143 (18%)	12/145 (8%)	2.4630 (1.1896, 5.0992) /0.015	9.9060 (2.1553, 17.6566) /0.012	2.1970 (1.1540, 4.1825) /0.017	0.842
35-<50	14/107 (13%)	8/109 (7%)	1.9005 (0.7626, 4.7366) /0.168	5.7447 (-2.3049, 13.7942) /0.162	1.7827 (0.7799, 4.0748) /0.170	
>=50	7/ 33 (21%)	4/ 29 (14%)	1.6827 (0.4382, 6.4622) /0.448	7.4190 (-11.3441, 26.1822) /0.438	1.5379 (0.5005, 4.7257) /0.452	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	12/143 (8%)	9/145 (6%)	1.3842 (0.5645, 3.3943) /0.477	2.1847 (-3.8215, 8.1909) /0.476	1.3520 (0.5879, 3.1093) /0.478	0.811
35-<50	12/107 (11%)	6/109 (6%)	2.1684 (0.7828, 6.0067) /0.137	5.7104 (-1.6435, 13.0643) /0.128	2.0374 (0.7935, 5.2313) /0.139	
>=50	4/ 33 (12%)	2/ 29 (7%)	1.8621 (0.3151, 11.0029) /0.493	5.2247 (-9.2340, 19.6833) /0.479	1.7576 (0.3470, 8.9026) /0.496	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness <35	8/143 (6%)	2/145 (1%)	4.2370 (0.8839, 20.3096) /0.071	4.2151 (-0.0029, 8.4331) /0.050	4.0559 (0.8763, 18.7718) /0.073	NC
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Paraesthesia <35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sciatica <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Migraine <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Amnesia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Disturbance in attention						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypoaesthesia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Intercostal neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Neuropathy peripheral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tension headache						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tremor						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Visual field defect						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	22/143 (15%)	15/145 (10%)	1.5758 (0.7814, 3.1777) /0.204	5.0398 (-2.6765, 12.7561) /0.201	1.4872 (0.8046, 2.7488) /0.205	0.737
35-<50	15/107 (14%)	8/109 (7%)	2.0584 (0.8341, 5.0800) /0.117	6.6792 (-1.5208, 14.8793) /0.110	1.9100 (0.8450, 4.3175) /0.120	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema <35	3/143 (2%)	3/145 (2%)	1.0143 (0.2013, 5.1111) /0.986	0.0289 (-3.2704, 3.3282) /0.986	1.0140 (0.2081, 4.9403) /0.986	0.836
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	0.415
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
<35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dermal cyst <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema <35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hyperhidrosis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Papule <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Alopecia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis allergic <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dyshidrotic eczema						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ephelides <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
<hr/>						
Granuloma annulare <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Lipodystrophy acquired						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Night sweats						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pityriasis alba						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Pruritus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Purpura <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rash macular						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rash papular						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rosacea <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin disorder <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin erosion <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hyperpigmentation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hypopigmentation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin induration						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin reaction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xeroderma <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	17/143 (12%)	17/145 (12%)	1.0159 (0.4965, 2.0784) /0.966	0.1640 (-7.2897, 7.6177) /0.966	1.0140 (0.5393, 1.9064) /0.966	0.609
35-<50	11/107 (10%)	8/109 (7%)	1.4466 (0.5580, 3.7503) /0.447	2.9409 (-4.6143, 10.4962) /0.446	1.4007 (0.5864, 3.3460) /0.448	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough <35	3/143 (2%)	5/145 (3%)	0.6000 (0.1407, 2.5589) /0.490	-1.3504 (-5.1369, 2.4362) /0.485	0.6084 (0.1481, 2.4984) /0.491	0.590
35-<50	2/107 (2%)	3/109 (3%)	0.6730 (0.1102, 4.1101) /0.668	-0.8831 (-4.8854, 3.1191) /0.665	0.6791 (0.1158, 3.9839) /0.668	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
<35	4/143 (3%)	4/145 (3%)	1.0144 (0.2488, 4.1365) /0.984	0.0386 (-3.7576, 3.8347) /0.984	1.0140 (0.2586, 3.9765) /0.984	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic <35	6/143 (4%)	1/145 (<1%)	6.3066 (0.7495, 53.0629) /0.090	3.5061 (-0.0453, 7.0576) /0.053	6.0839 (0.7418, 49.8995) /0.093	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion <35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea <35	0/143	3/145 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3430 (-21.3911, 12.7051) /0.618	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Bronchial obstruction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis chronic						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Bronchospasm						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nasal obstruction <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Reflux laryngitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tonsillar hypertrophy						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	13/143 (9%)	7/145 (5%)	1.9714 (0.7628, 5.0953) /0.161	4.2633 (-1.5996, 10.1262) /0.154	1.8831 (0.7738, 4.5826) /0.163	0.749
35-<50	11/107 (10%)	8/109 (7%)	1.4466 (0.5580, 3.7503) /0.447	2.9409 (-4.6143, 10.4962) /0.446	1.4007 (0.5864, 3.3460) /0.448	
>=50	2/ 33 (6%)	2/ 29 (7%)	0.8710 (0.1148, 6.6100) /0.894	-0.8359 (-13.1375, 11.4656) /0.894	0.8788 (0.1320, 5.8486) /0.894	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	0.592
35-<50	6/107 (6%)	1/109 (<1%)	6.4158 (0.7592, 54.2220) /0.088	4.6900 (-0.0223, 9.4024) /0.051	6.1121 (0.7484, 49.9195) /0.091	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Insomnia <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.561
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abnormal dreams						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	1/109 (<1%)	4.1942 (0.4611, 38.1515) /0.203	2.8209 (-1.1945, 6.8362) /0.169	4.0748 (0.4629, 35.8673) /0.206	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.582
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sleep disorder <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Nervousness <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Affect lability						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anxiety disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Paranoia <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	10/143 (7%)	9/145 (6%)	1.1362 (0.4475, 2.8846) /0.788	0.7861 (-4.9493, 6.5215) /0.788	1.1267 (0.4718, 2.6903) /0.788	0.486
35-<50	6/107 (6%)	10/109 (9%)	0.5881 (0.2059, 1.6796) /0.321	-3.5668 (-10.5216, 3.3880) /0.315	0.6112 (0.2302, 1.6226) /0.323	
>=50	2/ 33 (6%)	4/ 29 (14%)	0.4032 (0.0682, 2.3845) /0.317	-7.7325 (-22.6919, 7.2269) /0.311	0.4394 (0.0867, 2.2257) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
<35	1/143 (<1%)	3/145 (2%)	0.3333 (0.0343, 3.2429) /0.344	-1.3697 (-4.0591, 1.3198) /0.318	0.3380 (0.0356, 3.2112) /0.345	NC
35-<50	0/107	4/109 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8950 (-25.6249, 13.8350) /0.558	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Laceration <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Thermal burn <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin abrasion						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cranio-cerebral injury						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Epicondylitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Fall <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Foot fracture <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hand fracture <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Injury <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Limb injury						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Neck injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile contusion						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin injury						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Traumatic haematoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral injury <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	13/143 (9%)	8/145 (6%)	1.7125 (0.6874, 4.2665) /0.248	3.5737 (-2.4273, 9.5746) /0.243	1.6477 (0.7043, 3.8547) /0.249	0.085
35-<50	8/107 (7%)	7/109 (6%)	1.1775 (0.4115, 3.3695) /0.761	1.0546 (-5.7288, 7.8380) /0.761	1.1642 (0.4375, 3.0979) /0.761	
>=50	5/ 33 (15%)	0/ 29	>999 (>999, >999) /NC	16.8456 (-21.9090, 55.6001) /0.394	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency <35	10/143 (7%)	7/145 (5%)	1.4823 (0.5481, 4.0084) /0.438	2.1654 (-3.2792, 7.6101) /0.436	1.4486 (0.5671, 3.7003) /0.439	0.236
35-<50	8/107 (7%)	3/109 (3%)	2.8552 (0.7366, 11.0677) /0.129	4.7243 (-1.1296, 10.5782) /0.114	2.7165 (0.7405, 9.9659) /0.132	
>=50	3/ 33 (9%)	0/ 29	>999 (>999, >999) /NC	11.0748 (-27.1430, 49.2927) /0.570	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypovitaminosis						
<35	3/143 (2%)	1/145 (<1%)	3.0857 (0.3172, 30.0204) /0.332	1.4082 (-1.2995, 4.1160) /0.308	3.0420 (0.3202, 28.9004) /0.333	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glucose tolerance impaired						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hypocalcaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hypomagnesaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	6/143 (4%)	11/145 (8%)	0.5335 (0.1918, 1.4837) /0.229	-3.3904 (-8.8100, 2.0292) /0.220	0.5531 (0.2102, 1.4554) /0.230	0.061
35-<50	10/107 (9%)	4/109 (4%)	2.7062 (0.8217, 8.9126) /0.102	5.6761 (-0.8719, 12.2240) /0.089	2.5467 (0.8240, 7.8715) /0.104	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	4/143 (3%)	4/145 (3%)	1.0144 (0.2488, 4.1365) /0.984	0.0386 (-3.7576, 3.8347) /0.984	1.0140 (0.2586, 3.9765) /0.984	NC
35-<50	5/107 (5%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Melanocytic naevus <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral papilloma <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Uterine leiomyoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Benign spleen tumour						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dysplastic naevus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Lipoma						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neoplasm skin <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Oral fibroma <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	10/143 (7%)	7/145 (5%)	1.4823 (0.5481, 4.0084) /0.438	2.1654 (-3.2792, 7.6101) /0.436	1.4486 (0.5671, 3.7003) /0.439	0.265
35-<50	7/107 (7%)	4/109 (4%)	1.8375 (0.5219, 6.4690) /0.343	2.8723 (-2.9936, 8.7382) /0.337	1.7827 (0.5374, 5.9139) /0.345	
>=50	3/ 33 (9%)	0/ 29	>999 (>999, >999) /NC	11.0748 (-27.1430, 49.2927) /0.570	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<35	6/143 (4%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <35	2/143 (1%)	4/145 (3%)	0.5000 (0.0901, 2.7738) /0.428	-1.3600 (-4.6481, 1.9280) /0.418	0.5070 (0.0943, 2.7246) /0.429	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lipase increased <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose abnormal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin decreased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heart rate increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Protein urine present						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Total lung capacity decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Vitamin D increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Weight increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	8/143 (6%)	4/145 (3%)	2.0889 (0.6147, 7.0982) /0.238	2.8358 (-1.7788, 7.4504) /0.228	2.0280 (0.6245, 6.5852) /0.239	0.247
35-<50	4/107 (4%)	7/109 (6%)	0.5659 (0.1607, 1.9922) /0.375	-2.6837 (-8.5231, 3.1557) /0.368	0.5821 (0.1755, 1.9311) /0.376	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia <35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Erectile dysfunction <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital lesion						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Prostatitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Breast pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Menopausal symptoms <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Polymenorrhoea						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal dysplasia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal ulceration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Varicocele						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvar dysplasia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	5/143 (3%)	5/145 (3%)	1.0145 (0.2873, 3.5826) /0.982	0.0482 (-4.1808, 4.2773) /0.982	1.0140 (0.3000, 3.4273) /0.982	0.349
35-<50	6/107 (6%)	2/109 (2%)	3.1782 (0.6269, 16.1119) /0.163	3.7726 (-1.2623, 8.8076) /0.142	3.0561 (0.6308, 14.8063) /0.165	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.758
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	0/ 29	NC	NC	NC	
Eosinophilia <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Normocytic anaemia <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splenomegaly <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	6/143 (4%)	3/145 (2%)	2.0730 (0.5083, 8.4539) /0.309	2.1268 (-1.8939, 6.1476) /0.300	2.0280 (0.5171, 7.9530) /0.311	0.482
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Haematuria <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Calculus urinary						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Micturition urgency						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephrolithiasis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nephropathy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Proteinuria						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral caruncle						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Urinary incontinence <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
<35	6/143 (4%)	4/145 (3%)	1.5438 (0.4263, 5.5904) /0.508	1.4372 (-2.7943, 5.6686) /0.506	1.5210 (0.4384, 5.2764) /0.509	0.761
35-<50	2/107 (2%)	3/109 (3%)	0.6730 (0.1102, 4.1101) /0.668	-0.8831 (-4.8854, 3.1191) /0.665	0.6791 (0.1158, 3.9839) /0.668	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Asthenopia <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Astigmatism <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Blepharospasm <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dry eye						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye irritation <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Eye pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Glare <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meibomian gland dysfunction						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Myopia						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uveitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Vitreous detachment <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	6/143 (4%)	2/145 (1%)	3.1314 (0.6213, 15.7814) /0.167	2.8165 (-0.9785, 6.6115) /0.146	3.0420 (0.6244, 14.8210) /0.169	0.096
35-<50	1/107 (<1%)	3/109 (3%)	0.3333 (0.0341, 3.2561) /0.345	-1.8177 (-5.3894, 1.7540) /0.319	0.3396 (0.0359, 3.2133) /0.346	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.405
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vertigo <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	>0.999
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Noninfective myringitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	7/143 (5%)	1/145 (<1%)	7.4118 (0.9001, 61.0335) /0.063	4.2054 (0.4212, 7.9897) /0.029	7.0979 (0.8845, 56.9582) /0.065	0.521
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Seasonal allergy <35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mite allergy <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.114
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hypertension <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hyperaemia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intermittent claudication						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrioventricular block first degree						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gilbert's syndrome						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Keratosis follicular <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hypothyroidism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hepatitis toxic						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth extraction						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	73/143 (51%)	44/145 (30%)	2.3938 (1.4775, 3.8784) /<.001	20.7041 (9.6079, 31.8003) /<.001	1.6823 (1.2535, 2.2578) /<.001	0.166
35-<50	52/107 (49%)	35/109 (32%)	1.9990 (1.1503, 3.4738) /0.014	16.4880 (3.5841, 29.3919) /0.012	1.5135 (1.0822, 2.1166) /0.015	
>=50	18/ 33 (55%)	16/ 29 (55%)	0.9750 (0.3578, 2.6571) /0.961	-0.6270 (-25.4510, 24.1970) /0.961	0.9886 (0.6289, 1.5542) /0.961	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	31/143 (22%)	21/145 (14%)	1.6344 (0.8880, 3.0080) /0.114	7.1956 (-1.6601, 16.0512) /0.111	1.4968 (0.9047, 2.4765) /0.116	0.066
35-<50	19/107 (18%)	16/109 (15%)	1.2550 (0.6071, 2.5941) /0.540	3.0781 (-6.7488, 12.9051) /0.539	1.2097 (0.6578, 2.2246) /0.540	
>=50	6/ 33 (18%)	11/ 29 (38%)	0.3636 (0.1140, 1.1598) /0.087	-19.7492 (-41.7727, 2.2743) /0.079	0.4793 (0.2027, 1.1334) /0.094	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
<35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	0.582
35-<50	2/107 (2%)	2/109 (2%)	1.0190 (0.1409, 7.3687) /0.985	0.0343 (-3.5620, 3.6305) /0.985	1.0187 (0.1461, 7.1011) /0.985	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection <35	3/143 (2%)	3/145 (2%)	1.0143 (0.2013, 5.1111) /0.986	0.0289 (-3.2704, 3.3282) /0.986	1.0140 (0.2081, 4.9403) /0.986	0.864
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	0.904
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	3/109 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0095 (-24.7142, 14.6951) /0.618	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.917
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	2/ 33 (6%)	3/ 29 (10%)	0.5591 (0.0867, 3.6046) /0.541	-4.2842 (-18.0367, 9.4683) /0.541	0.5859 (0.1051, 3.2660) /0.542	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Folliculitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Furuncle <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.405
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Urethritis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oropharyngeal gonococcal infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chlamydial infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Proctitis gonococcal <35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tooth abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethritis gonococcal						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	>0.999
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Proctitis chlamydial <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Acarodermatitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Orchitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin infection <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Escherichia urinary tract infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pneumonia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Acute hepatitis B <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital candidiasis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary chlamydia infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract gonococcal infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hepatitis E						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphogranuloma venereum						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Malaria						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis mycoplasma <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Urethritis mycoplasmal						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Varicella						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	51/143 (36%)	2/145 (1%)	39.6356 (9.4200, 166.7709) /<.001	34.2850 (26.2078, 42.3622) /<.001	25.8566 (6.4158, 104.2064) /<.001	NC
35-<50	34/107 (32%)	1/109 (<1%)	50.3014 (6.7356, 375.6518) /<.001	30.8583 (21.8564, 39.8601) /<.001	34.6355 (4.8272, 248.5113) /<.001	
>=50	11/ 33 (33%)	1/ 29 (3%)	14.0000 (1.6772, 116.8586) /0.015	29.8851 (12.4843, 47.2858) /<.001	9.6666 (1.3275, 70.3919) /0.025	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	48/143 (34%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	33/107 (31%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	11/ 33 (33%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration <35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	3/143 (2%)	2/145 (1%)	1.5321 (0.2522, 9.3089) /0.643	0.7186 (-2.3015, 3.7387) /0.641	1.5210 (0.2580, 8.9672) /0.643	0.330
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Malaise <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Injection site haematoma <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Catheter site erythema						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	15/143 (10%)	5/145 (3%)	3.2812 (1.1596, 9.2844) /0.025	7.0412 (1.2066, 12.8759) /0.018	3.0420 (1.1355, 8.1491) /0.027	0.425
35-<50	15/107 (14%)	4/109 (4%)	4.2799 (1.3717, 13.3540) /0.012	10.3490 (2.8836, 17.8144) /0.007	3.8201 (1.3101, 11.1392) /0.014	
>=50	4/ 33 (12%)	3/ 29 (10%)	1.1954 (0.2443, 5.8490) /0.826	1.7764 (-13.9352, 17.4880) /0.825	1.1717 (0.2857, 4.8059) /0.826	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	6/143 (4%)	1/145 (<1%)	6.3066 (0.7495, 53.0629) /0.090	3.5061 (-0.0453, 7.0576) /0.053	6.0839 (0.7418, 49.8995) /0.093	0.527
35-<50	5/107 (5%)	2/109 (2%)	2.6225 (0.4976, 13.8218) /0.256	2.8380 (-1.8885, 7.5646) /0.239	2.5467 (0.5050, 12.8430) /0.257	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abdominal pain						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Toothache <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation <35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal fissure <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal haemorrhage						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Abdominal distension						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal inflammation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Faeces soft						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rectal haemorrhage						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea haemorrhagic <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Barrett's oesophagus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pancreatitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia oral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth development disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	7/143 (5%)	5/145 (3%)	1.4412 (0.4466, 4.6511) /0.541	1.4468 (-3.1712, 6.0649) /0.539	1.4196 (0.4613, 4.3689) /0.541	0.970
35-<50	5/107 (5%)	3/109 (3%)	1.7320 (0.4035, 7.4353) /0.460	1.9206 (-3.1217, 6.9630) /0.455	1.6978 (0.4161, 6.9284) /0.461	
>=50	4/ 33 (12%)	2/ 29 (7%)	1.8621 (0.3151, 11.0029) /0.493	5.2247 (-9.2340, 19.6833) /0.479	1.7576 (0.3470, 8.9026) /0.496	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <35	5/143 (3%)	2/145 (1%)	2.5906 (0.4943, 13.5758) /0.260	2.1172 (-1.4420, 5.6764) /0.244	2.5350 (0.4999, 12.8540) /0.261	0.330
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myalgia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle spasms <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Neck pain						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondros						
is						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoporosis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Rotator cuff syndrome <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	9/143 (6%)	4/145 (3%)	2.3675 (0.7122, 7.8707) /0.160	3.5351 (-1.2555, 8.3257) /0.148	2.2815 (0.7189, 7.2408) /0.162	0.499
35-<50	6/107 (6%)	5/109 (5%)	1.2356 (0.3655, 4.1770) /0.733	1.0203 (-4.8472, 6.8878) /0.733	1.2224 (0.3846, 3.8857) /0.734	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	6/143 (4%)	2/145 (1%)	3.1314 (0.6213, 15.7814) /0.167	2.8165 (-0.9785, 6.6115) /0.146	3.0420 (0.6244, 14.8210) /0.169	0.707
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Migraine <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Amnesia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dysarthria <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Anosmia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Cervical neuritis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nerve compression <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigeminal neuralgia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	4/143 (3%)	2/145 (1%)	2.0576 (0.3709, 11.4144) /0.409	1.4179 (-1.8848, 4.7206) /0.400	2.0280 (0.3774, 10.8985) /0.410	0.147
35-<50	3/107 (3%)	3/109 (3%)	1.0192 (0.2011, 5.1658) /0.982	0.0514 (-4.3322, 4.4351) /0.982	1.0187 (0.2103, 4.9354) /0.982	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hyperhidrosis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Dyshidrotic eczema						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Urticaria						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nail pigmentation <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash morbilliform <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	7/143 (5%)	2/145 (1%)	3.6801 (0.7513, 18.0266) /0.108	3.5158 (-0.4979, 7.5295) /0.086	3.5490 (0.7500, 16.7945) /0.110	0.476
35-<50	4/107 (4%)	4/109 (4%)	1.0194 (0.2483, 4.1851) /0.979	0.0686 (-4.9691, 5.1062) /0.979	1.0187 (0.2615, 3.9690) /0.979	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cough <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.929
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	2/ 33 (6%)	1/ 29 (3%)	1.8065 (0.1552, 21.0228) /0.637	2.6123 (-7.8937, 13.1184) /0.626	1.7576 (0.1679, 18.3931) /0.638	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh <35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nasal congestion <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Respiratory disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal turbinates hypertrophy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	4/143 (3%)	5/145 (3%)	0.8058 (0.2119, 3.0636) /0.751	-0.6511 (-4.6666, 3.3645) /0.751	0.8112 (0.2223, 2.9597) /0.751	0.450
35-<50	3/107 (3%)	3/109 (3%)	1.0192 (0.2011, 5.1658) /0.982	0.0514 (-4.3322, 4.4351) /0.982	1.0187 (0.2103, 4.9354) /0.982	
>=50	4/ 33 (12%)	1/ 29 (3%)	3.8621 (0.4062, 36.7155) /0.240	8.6729 (-4.2924, 21.6383) /0.190	3.5151 (0.4162, 29.6910) /0.248	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.996
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	0.151
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	2/ 33 (6%)	0/ 29	>999 (>999, >999) /NC	8.1845 (-29.7522, 46.1212) /0.672	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Panic attack <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Affective disorder						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Drug abuse						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	7/143 (5%)	4/145 (3%)	1.8143 (0.5194, 6.3381) /0.351	2.1365 (-2.2922, 6.5651) /0.344	1.7745 (0.5310, 5.9302) /0.352	0.033
35-<50	1/107 (<1%)	7/109 (6%)	0.1375 (0.0166, 1.1371) /0.066	-5.4874 (-10.4375, -0.5373) /0.030	0.1455 (0.0182, 1.1628) /0.069	
>=50	3/ 33 (9%)	1/ 29 (3%)	2.8000 (0.2749, 28.5213) /0.385	5.6426 (-6.2025, 17.4878) /0.350	2.6364 (0.2899, 23.9723) /0.389	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Fall						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Limb injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Wound <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
<hr/>						
Ankle fracture <35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Meniscus injury <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure via inhalation						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fracture <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Joint dislocation <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rib fracture <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	
Tendon injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tibia fracture						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	1/143 (<1%)	4/145 (3%)	0.2482 (0.0274, 2.2486) /0.215	-2.0593 (-5.0547, 0.9360) /0.178	0.2535 (0.0287, 2.2405) /0.217	0.144
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.932
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Type 2 diabetes mellitus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Gout						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	0.161
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	1/ 33 (3%)	2/ 29 (7%)	0.4219 (0.0362, 4.9108) /0.491	-3.8662 (-14.7869, 7.0544) /0.488	0.4394 (0.0420, 4.5983) /0.492	
Anogenital warts <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Anal neoplasm <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Breast cancer <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Kaposi's sarcoma <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kidney angiomyolipom						
a						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	5/143 (3%)	4/145 (3%)	1.2772 (0.3359, 4.8560) /0.720	0.7379 (-3.2834, 4.7592) /0.719	1.2675 (0.3474, 4.6245) /0.720	0.575
35-<50	4/107 (4%)	4/109 (4%)	1.0194 (0.2483, 4.1851) /0.979	0.0686 (-4.9691, 5.1062) /0.979	1.0187 (0.2615, 3.9690) /0.979	
>=50	2/ 33 (6%)	4/ 29 (14%)	0.4032 (0.0682, 2.3845) /0.317	-7.7325 (-22.6919, 7.2269) /0.311	0.4394 (0.0867, 2.2257) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	0.244
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Aortic bruit						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood folate decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma test positive <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Platelet count decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Treponema test positive						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	2/143 (1%)	3/145 (2%)	0.6714 (0.1105, 4.0792) /0.665	-0.6704 (-3.6824, 2.3417) /0.663	0.6760 (0.1147, 3.9854) /0.665	0.543
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Erectile dysfunction <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Prostatitis <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Ovarian cyst						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Testicular pain <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	0.561
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	
Eosinophilia <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypochromic anaemia						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Renal failure <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	2/109 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1119 (-23.8244, 15.6006) /0.683	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Chalazion <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chorioretinal disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Diabetic retinopathy						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Glaucoma <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	4/107 (4%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Circulatory collapse						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertensive crisis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Goitre <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	3/107 (3%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbilirubi naemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic steatosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Hydrocholecystis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	11/143 (8%)	5/145 (3%)	2.3333 (0.7896, 6.8953) /0.125	4.2440 (-1.0375, 9.5256) /0.115	2.2308 (0.7951, 6.2584) /0.127	0.747
35-<50	9/107 (8%)	3/109 (3%)	3.2449 (0.8538, 12.3330) /0.084	5.6589 (-0.4313, 11.7491) /0.069	3.0561 (0.8504, 10.9820) /0.087	
>=50	3/ 33 (9%)	2/ 29 (7%)	1.3500 (0.2095, 8.6999) /0.752	2.1944 (-11.2689, 15.6576) /0.749	1.3182 (0.2365, 7.3485) /0.753	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	1/143 (<1%)	2/145 (1%)	0.5035 (0.0451, 5.6155) /0.577	-0.6800 (-3.0186, 1.6586) /0.569	0.5070 (0.0465, 5.5293) /0.577	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Acute hepatitis B <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	8/143 (6%)	1/145 (<1%)	8.5333 (1.0533, 69.1345) /0.045	4.9048 (0.9045, 8.9050) /0.016	8.1119 (1.0277, 64.0275) /0.047	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	8/143 (6%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertebral foraminal stenosis <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal column injury						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hyperlipasaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adenocarcinoma of colon						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Skin cancer						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/143 (1%)	1/145 (<1%)	2.0426 (0.1831, 22.7795) /0.562	0.7089 (-1.6403, 3.0582) /0.554	2.0280 (0.1859, 22.1171) /0.562	0.367
35-<50	3/107 (3%)	2/109 (2%)	1.5433 (0.2527, 9.4247) /0.638	0.9689 (-3.0475, 4.9853) /0.636	1.5280 (0.2605, 8.9637) /0.639	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Cholecystitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic cirrhosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	4/143 (3%)	0/145	>999 (>999, >999) /NC	5.0531 (-11.8955, 22.0016) /0.559	>999 (>999, >999) /NC	0.416
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Road traffic accident <35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis <35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	24/ 63 (38%)	20/ 64 (31%)	1.3538 (0.6502, 2.8190) /0.418	6.8452 (-9.6700, 23.3605) /0.417	1.2190 (0.7537, 1.9716) /0.419	0.040
Male	69/220 (31%)	99/219 (45%)	0.5539 (0.3751, 0.8179) /0.003	-13.8418 (-22.8439, -4.8398) /0.003	0.6938 (0.5437, 0.8854) /0.003	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
Female	25/ 63 (40%)	21/ 64 (33%)	1.3471 (0.6518, 2.7841) /0.421	6.8700 (-9.8115, 23.5516) /0.420	1.2094 (0.7602, 1.9240) /0.422	0.567
Male	107/220 (49%)	102/219 (47%)	1.0862 (0.7467, 1.5799) /0.666	2.0610 (-7.2807, 11.4027) /0.665	1.0443 (0.8581, 1.2708) /0.666	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	9/ 63 (14%)	8/ 64 (13%)	1.1667 (0.4194, 3.2455) /0.768	1.7857 (-10.0597, 13.6311) /0.768	1.1429 (0.4709, 2.7735) /0.768	0.987
Male	41/220 (19%)	36/219 (16%)	1.1643 (0.7113, 1.9059) /0.545	2.1980 (-4.9133, 9.3094) /0.545	1.1337 (0.7549, 1.7027) /0.545	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	7/ 63 (11%)	6/ 64 (9%)	1.2083 (0.3824, 3.8184) /0.747	1.7361 (-8.8099, 12.2821) /0.747	1.1852 (0.4217, 3.3313) /0.747	0.728
Male	25/220 (11%)	17/219 (8%)	1.5234 (0.7978, 2.9088) /0.202	3.6011 (-1.8895, 9.0917) /0.199	1.4639 (0.8139, 2.6331) /0.203	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.091
Male	16/220 (7%)	17/219 (8%)	0.9319 (0.4582, 1.8953) /0.846	-0.4898 (-5.4229, 4.4432) /0.846	0.9369 (0.4859, 1.8065) /0.846	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.794
Male	12/220 (5%)	8/219 (4%)	1.5216 (0.6095, 3.7986) /0.368	1.8016 (-2.0944, 5.6975) /0.365	1.4932 (0.6226, 3.5813) /0.369	
Pharyngitis						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.129
Male	11/220 (5%)	9/219 (4%)	1.2281 (0.4985, 3.0251) /0.655	0.8904 (-3.0091, 4.7900) /0.654	1.2167 (0.5144, 2.8776) /0.655	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
Female	4/ 63 (6%)	3/ 64 (5%)	1.3785 (0.2958, 6.4247) /0.683	1.6617 (-6.2802, 9.6036) /0.682	1.3545 (0.3158, 5.8090) /0.683	0.795
Male	7/220 (3%)	4/219 (2%)	1.7664 (0.5096, 6.1224) /0.370	1.3553 (-1.5643, 4.2750) /0.363	1.7420 (0.5173, 5.8662) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.529
Male	8/220 (4%)	7/219 (3%)	1.1429 (0.4072, 3.2079) /0.800	0.4400 (-2.9579, 3.8380) /0.800	1.1377 (0.4198, 3.0831) /0.800	
Syphilis Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	8/220 (4%)	6/219 (3%)	1.3396 (0.4570, 3.9268) /0.594	0.8966 (-2.3886, 4.1819) /0.593	1.3273 (0.4683, 3.7620) /0.594	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.307
Male	7/220 (3%)	5/219 (2%)	1.4066 (0.4395, 4.5013) /0.565	0.8987 (-2.1496, 3.9471) /0.563	1.3936 (0.4492, 4.3241) /0.566	
Folliculitis Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.820
Male	6/220 (3%)	4/219 (2%)	1.5070 (0.4193, 5.4160) /0.530	0.9008 (-1.8880, 3.6896) /0.527	1.4932 (0.4273, 5.2182) /0.530	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.553
Male	3/220 (1%)	4/219 (2%)	0.7431 (0.1644, 3.3597) /0.700	-0.4628 (-2.8068, 1.8811) /0.699	0.7466 (0.1691, 3.2969) /0.700	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.388
Male	5/220 (2%)	3/219 (1%)	1.6744 (0.3952, 7.0938) /0.484	0.9029 (-1.5968, 3.4025) /0.479	1.6591 (0.4014, 6.8575) /0.484	
Gonorrhoea						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	5/219 (2%)	0.9953 (0.2840, 3.4879) /0.994	-0.0104 (-2.8017, 2.7810) /0.994	0.9955 (0.2923, 3.3900) /0.994	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.290
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.043
Male	2/220 (<1%)	5/219 (2%)	0.3927 (0.0754, 2.0459) /0.267	-1.3740 (-3.7163, 0.9683) /0.250	0.3982 (0.0781, 2.0305) /0.268	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.683
Male	4/220 (2%)	2/219 (<1%)	2.0093 (0.3642, 11.0847) /0.423	0.9049 (-1.2640, 3.0739) /0.414	1.9909 (0.3685, 10.7578) /0.424	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.245
Male	2/220 (<1%)	4/219 (2%)	0.4931 (0.0894, 2.7204) /0.417	-0.9174 (-3.0895, 1.2548) /0.408	0.4977 (0.0921, 2.6894) /0.418	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.023
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.838
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.063
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
Female	1/ 63 (2%)	4/ 64 (6%)	0.2419 (0.0263, 2.2273) /0.210	-4.6627 (-11.3481, 2.0227) /0.172	0.2540 (0.0292, 2.2100) /0.214	0.307
Male	0/220	3/219 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hordeolum						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	2/219 (<1%)	2.5233 (0.4843, 13.1469) /0.272	1.3595 (-0.9784, 3.6973) /0.254	2.4886 (0.4880, 12.6905) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.209
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	
Herpes zoster						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	6/220 (3%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.399
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Pharyngotonsillitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	
Anal chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.025
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	3/ 63 (5%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.132
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Sinusitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.185
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.405
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oropharyngeal gonococcal infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.31111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Subcutaneous abscess						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.992
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ureaplasma infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.992
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Chlamydial infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genital herpes simplex Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Proctitis gonococcal						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Tooth abscess						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.049
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheobronchitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	3/219 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Urethritis gonococcal						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Viral upper respiratory tract infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Balanitis candida						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic tonsillitis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Mycoplasma infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis externa						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis chlamydial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethritis chlamydial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Abscess limb						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Acute sinusitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Angular cheilitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anorectal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vulvovaginitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Bronchitis pneumococcal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cat scratch disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Conjunctivitis bacterial						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dacryocystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fungal infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis shigella						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastrointestinal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Genitourinary tract infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Groin abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter gastritis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Herpes virus infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Impetigo						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Infectious colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site abscess						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Lice infestation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Onychomycosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oophoritis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oral infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Orchitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Otitis media						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Paronychia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Pertussis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyelonephritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis chronic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Respiratory tract infection bacterial						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Sexually transmitted disease						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Strongyloidiasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tonsillitis bacterial						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Upper respiratory tract infection bacterial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Viral tonsillitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	35/ 63 (56%)	4/ 64 (6%)	18.7500 (6.0718, 57.9008) /<.001	49.3056 (35.6774, 62.9337) /<.001	8.8889 (3.3554, 23.5478) /<.001	0.444
Male	101/220 (46%)	17/219 (8%)	10.0850 (5.7519, 17.6824) /<.001	38.1465 (30.6686, 45.6245) /<.001	5.9142 (3.6649, 9.5438) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	24/ 63 (38%)	0/ 64	>999 (>999, >999) /NC	38.6749 (11.3684, 65.9815) /0.006	>999 (>999, >999) /NC	NC
Male	100/220 (45%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	9/ 63 (14%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	30/220 (14%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site induration						
Female	17/ 63 (27%)	0/ 64	>999 (>999, >999) /NC	28.1047 (1.1510, 55.0583) /0.041	>999 (>999, >999) /NC	NC
Male	12/220 (5%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
Female	4/ 63 (6%)	0/ 64	>999 (>999, >999) /NC	8.4601 (-17.2551, 34.1754) /0.519	>999 (>999, >999) /NC	NC
Male	15/220 (7%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.607
Male	14/220 (6%)	2/219 (<1%)	7.3738 (1.6555, 32.8431) /0.009	5.4504 (1.9875, 8.9133) /0.002	6.9682 (1.6026, 30.2982) /0.010	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
Female	8/ 63 (13%)	0/ 64	>999 (>999, >999) /NC	14.5108 (-11.6545, 40.6760) /0.277	>999 (>999, >999) /NC	NC
Male	8/220 (4%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.986
Male	5/220 (2%)	5/219 (2%)	0.9953 (0.2840, 3.4879) /0.994	-0.0104 (-2.8017, 2.7810) /0.994	0.9955 (0.2923, 3.3900) /0.994	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.287
Male	5/220 (2%)	6/219 (3%)	0.8256 (0.2482, 2.7461) /0.755	-0.4670 (-3.3914, 2.4574) /0.754	0.8295 (0.2570, 2.6781) /0.755	
Asthenia Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	10/220 (5%)	1/219 (<1%)	10.3810 (1.3174, 81.8033) /0.026	4.0888 (1.1951, 6.9825) /0.006	9.9545 (1.2852, 77.1015) /0.028	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
Female	5/ 63 (8%)	0/ 64	>999 (>999, >999) /NC	9.9745 (-15.8545, 35.8035) /0.449	>999 (>999, >999) /NC	NC
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Malaise						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.105
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.308
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haemorrhage						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site anaesthesia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cyst						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site discolouration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site granuloma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Injection site necrosis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site scar						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Non-cardiac chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Swelling						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vessel puncture site bruise						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	10/ 63 (16%)	14/ 64 (22%)	0.6739 (0.2743, 1.6554) /0.389	-6.0020 (-19.5667, 7.5627) /0.386	0.7256 (0.3486, 1.5105) /0.391	0.158
Male	62/220 (28%)	48/219 (22%)	1.3979 (0.9053, 2.1586) /0.131	6.2640 (-1.8206, 14.3486) /0.129	1.2858 (0.9271, 1.7833) /0.132	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	3/ 63 (5%)	2/ 64 (3%)	1.5500 (0.2501, 9.6053) /0.638	1.6369 (-5.1325, 8.4063) /0.636	1.5238 (0.2635, 8.8133) /0.638	0.568
Male	17/220 (8%)	19/219 (9%)	0.8815 (0.4453, 1.7450) /0.717	-0.9485 (-6.0816, 4.1845) /0.717	0.8907 (0.4758, 1.6673) /0.717	
Nausea						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.858
Male	13/220 (6%)	8/219 (4%)	1.6564 (0.6725, 4.0796) /0.272	2.2561 (-1.7291, 6.2413) /0.267	1.6176 (0.6841, 3.8251) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.929
Male	7/220 (3%)	6/219 (3%)	1.1667 (0.3857, 3.5289) /0.785	0.4421 (-2.7286, 3.6128) /0.785	1.1614 (0.3967, 3.4002) /0.785	
Haemorrhoids						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.427
Male	11/220 (5%)	2/219 (<1%)	5.7105 (1.2508, 26.0723) /0.025	4.0868 (0.9433, 7.2302) /0.011	5.4750 (1.2278, 24.4143) /0.026	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.345
Male	5/220 (2%)	3/219 (1%)	1.6744 (0.3952, 7.0938) /0.484	0.9029 (-1.5968, 3.4025) /0.479	1.6591 (0.4014, 6.8575) /0.484	
Toothache Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	6/220 (3%)	3/219 (1%)	2.0187 (0.4984, 8.1759) /0.325	1.3574 (-1.2888, 4.0036) /0.315	1.9909 (0.5043, 7.8602) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.386
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.105
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.048
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	
Dental caries						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Odynophagia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.209
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.136
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.136
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.278
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Proctitis Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.190
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroesophageal reflux disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.412
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Abdominal pain lower						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.308
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastroduodeni tis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival bleeding						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haemorrhoidal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Stomatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Abdominal distension						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Aerophagia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal inflammation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Bile acid malabsorption						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bowel movement irregularity						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis microscopic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysbacteriosiss						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Enteritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Enterocolitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Epigastric discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastrointestinal sounds abnormal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gingival swelling						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Inguinal hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Leukoplakia oral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphoid hyperplasia of intestine						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oesophageal polyp						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Palatal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rectal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	9/ 63 (14%)	10/ 64 (16%)	0.9000 (0.3390, 2.3893) /0.832	-1.3393 (-13.7407, 11.0621) /0.832	0.9143 (0.3984, 2.0981) /0.833	0.289
Male	37/220 (17%)	24/219 (11%)	1.6428 (0.9460, 2.8527) /0.078	5.8593 (-0.5862, 12.3047) /0.075	1.5347 (0.9511, 2.4762) /0.079	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain Female	4/ 63 (6%)	3/ 64 (5%)	1.3785 (0.2958, 6.4247) /0.683	1.6617 (-6.2802, 9.6036) /0.682	1.3545 (0.3158, 5.8090) /0.683	0.740
Male	11/220 (5%)	6/219 (3%)	1.8684 (0.6786, 5.1446) /0.226	2.2603 (-1.3409, 5.8614) /0.219	1.8250 (0.6870, 4.8479) /0.227	
Myalgia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.435
Male	11/220 (5%)	4/219 (2%)	2.8289 (0.8867, 9.0251) /0.079	3.1735 (-0.2087, 6.5557) /0.066	2.7375 (0.8852, 8.4657) /0.080	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.507
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.051
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	0.343
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Musculoskeletal chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck pain						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal discomfort						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteochondros is						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Spinal disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Bursitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Groin pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Joint swelling						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Soft tissue mass Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Tendon pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	9/ 63 (14%)	7/ 64 (11%)	1.3571 (0.4723, 3.8997) /0.571	3.3482 (-8.1901, 14.8866) /0.570	1.3061 (0.5182, 3.2921) /0.571	0.334
Male	38/220 (17%)	17/219 (8%)	2.4809 (1.3535, 4.5476) /0.003	9.5102 (3.3856, 15.6347) /0.002	2.2251 (1.2961, 3.8200) /0.004	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	3/ 63 (5%)	4/ 64 (6%)	0.7500 (0.1609, 3.4954) /0.714	-1.4881 (-9.4142, 6.4380) /0.713	0.7619 (0.1777, 3.2675) /0.714	0.254
Male	25/220 (11%)	13/219 (6%)	2.0316 (1.0106, 4.0838) /0.047	5.4276 (0.1948, 10.6603) /0.042	1.9143 (1.0058, 3.6434) /0.048	
Dizziness Female	5/ 63 (8%)	2/ 64 (3%)	2.6724 (0.4988, 14.3169) /0.251	4.8115 (-3.1083, 12.7313) /0.234	2.5397 (0.5115, 12.6106) /0.254	0.377
Male	8/220 (4%)	1/219 (<1%)	8.2264 (1.0201, 66.3395) /0.048	3.1797 (0.5499, 5.8096) /0.018	7.9636 (1.0045, 63.1368) /0.050	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Sciatica						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Migraine Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Somnolence						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Amnesia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Autonomic nervous system imbalance						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Disturbance in attention						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoaesthesia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Neuropathy peripheral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Poor quality sleep						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Post herpetic neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tension headache						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tremor						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Visual field defect						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Skin and subcutaneous tissue disorders						
Any Event						
Female	4/ 63 (6%)	4/ 64 (6%)	1.0169 (0.2429, 4.2569) /0.982	0.0992 (-8.3522, 8.5506) /0.982	1.0159 (0.2656, 3.8856) /0.982	0.504
Male	35/220 (16%)	21/219 (10%)	1.7838 (1.0018, 3.1761) /0.049	6.3200 (0.1098, 12.5303) /0.046	1.6591 (0.9986, 2.7563) /0.051	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Eczema						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.280
Male	6/220 (3%)	5/219 (2%)	1.2000 (0.3608, 3.9915) /0.766	0.4442 (-2.4791, 3.3675) /0.766	1.1945 (0.3700, 3.8564) /0.766	
Rash						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.223
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Acne						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Seborrhoeic dermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Skin lesion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Erythema						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Intertrigo						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papule Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pityriasis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash pruritic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Alopecia						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dermatitis allergic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dyshidrotic eczema						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ephelides Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Granuloma annulare Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipodystrophy acquired						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Night sweats						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile ulceration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pityriasis alba						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Psoriasis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Rash generalised Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash maculo-papular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash vesicular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin erosion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin hyperpigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypopigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin induration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin reaction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Xeroderma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	4/ 63 (6%)	3/ 64 (5%)	1.3785 (0.2958, 6.4247) /0.683	1.6617 (-6.2802, 9.6036) /0.682	1.3545 (0.3158, 5.8090) /0.683	0.734
Male	25/220 (11%)	24/219 (11%)	1.0417 (0.5750, 1.8871) /0.893	0.4047 (-5.4863, 6.2957) /0.893	1.0369 (0.6116, 1.7580) /0.893	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.469
Male	3/220 (1%)	7/219 (3%)	0.4187 (0.1069, 1.6406) /0.211	-1.8327 (-4.6213, 0.9559) /0.198	0.4266 (0.1118, 1.6285) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.172
Male	6/220 (3%)	4/219 (2%)	1.5070 (0.4193, 5.4160) /0.530	0.9008 (-1.8880, 3.6896) /0.527	1.4932 (0.4273, 5.2182) /0.530	
Rhinitis allergic						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	7/220 (3%)	1/219 (<1%)	7.1643 (0.8740, 58.7267) /0.067	2.7252 (0.2400, 5.2104) /0.032	6.9682 (0.8645, 56.1638) /0.068	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	
Nasal congestion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	4/219 (2%)	0.2454 (0.0272, 2.2136) /0.211	-1.3719 (-3.3557, 0.6118) /0.175	0.2489 (0.0280, 2.2088) /0.212	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	4/219 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Asthma Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Productive cough						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchial obstruction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis chronic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchospasm						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal obstruction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Reflux laryngitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Tonsillar hypertrophy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Wheezing						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	4/ 63 (6%)	3/ 64 (5%)	1.3785 (0.2958, 6.4247) /0.683	1.6617 (-6.2802, 9.6036) /0.682	1.3545 (0.3158, 5.8090) /0.683	0.860
Male	22/220 (10%)	14/219 (6%)	1.6270 (0.8096, 3.2697) /0.172	3.6073 (-1.5124, 8.7270) /0.167	1.5643 (0.8220, 2.9768) /0.173	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.432
Male	8/220 (4%)	3/219 (1%)	2.7170 (0.7112, 10.3800) /0.144	2.2665 (-0.6470, 5.1800) /0.127	2.6545 (0.7136, 9.8741) /0.145	
Insomnia Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.369
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	5/220 (2%)	1/219 (<1%)	5.0698 (0.5874, 43.7537) /0.140	1.8161 (-0.3462, 3.9784) /0.100	4.9773 (0.5863, 42.2560) /0.141	
Depression						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Sleep disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.278
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Depressed mood						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Adjustment disorder						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Nightmare						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Suicidal ideation Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Affect lability						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Intentional self-injury						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paranoia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	3/ 63 (5%)	3/ 64 (5%)	1.0167 (0.1973, 5.2385) /0.984	0.0744 (-7.3060, 7.4548) /0.984	1.0159 (0.2130, 4.8442) /0.984	0.721
Male	15/220 (7%)	20/219 (9%)	0.7280 (0.3625, 1.4621) /0.372	-2.3142 (-7.3788, 2.7503) /0.370	0.7466 (0.3926, 1.4198) /0.373	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.595
Male	1/220 (<1%)	6/219 (3%)	0.1621 (0.0194, 1.3578) /0.093	-2.2852 (-4.6227, 0.0524) /0.055	0.1659 (0.0201, 1.3667) /0.095	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.522
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Laceration Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Arthropod sting						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Penis injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin abrasion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Cranio-cerebral injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epicondylitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Fall						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hand fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Limb injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile contusion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post procedural haemorrhage						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Soft tissue injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Traumatic haematoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethral injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	5/ 63 (8%)	2/ 64 (3%)	2.6724 (0.4988, 14.3169) /0.251	4.8115 (-3.1083, 12.7313) /0.234	2.5397 (0.5115, 12.6106) /0.254	0.597
Male	21/220 (10%)	13/219 (6%)	1.6722 (0.8151, 3.4306) /0.161	3.6094 (-1.3777, 8.5964) /0.156	1.6080 (0.8262, 3.1296) /0.162	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Vitamin D deficiency						
Female	4/ 63 (6%)	0/ 64	>999 (>999, >999) /NC	8.4601 (-17.2551, 34.1754) /0.519	>999 (>999, >999) /NC	0.061
Male	17/220 (8%)	10/219 (5%)	1.7502 (0.7828, 3.9133) /0.173	3.1611 (-1.3216, 7.6437) /0.167	1.6923 (0.7927, 3.6126) /0.174	
Hypovitaminosis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypertriglyceridaemia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glucose tolerance impaired						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperlipasaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypocalcaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypokalaemia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypomagnesaemia						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Hypophosphataemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Iron deficiency						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lactose intolerance						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Type 2 diabetes mellitus						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.601
Male	15/220 (7%)	14/219 (6%)	1.0714 (0.5043, 2.2765) /0.858	0.4255 (-4.2210, 5.0720) /0.858	1.0666 (0.5276, 2.1562) /0.858	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Anogenital warts						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	11/220 (5%)	4/219 (2%)	2.8289 (0.8867, 9.0251) /0.079	3.1735 (-0.2087, 6.5557) /0.066	2.7375 (0.8852, 8.4657) /0.080	
Skin papilloma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Acrochordon						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Melanocytic naevus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oral papilloma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Uterine leiomyoma						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Benign spleen tumour						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysplastic naevus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lipoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Neoplasm skin						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oral fibroma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Investigations						
Any Event						
Female	5/ 63 (8%)	4/ 64 (6%)	1.2931 (0.3308, 5.0554) /0.712	1.6865 (-7.2422, 10.6152) /0.711	1.2698 (0.3573, 4.5124) /0.712	0.511
Male	15/220 (7%)	7/219 (3%)	2.2160 (0.8854, 5.5466) /0.089	3.6218 (-0.4428, 7.6864) /0.081	2.1331 (0.8871, 5.1295) /0.091	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	8/220 (4%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.343
Male	2/220 (<1%)	3/219 (1%)	0.6606 (0.1093, 3.9923) /0.651	-0.4608 (-2.4464, 1.5249) /0.649	0.6636 (0.1120, 3.9329) /0.652	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose abnormal						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Blood creatinine increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carbon dioxide decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Creatinine renal clearance decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Electrocardiogram repolarisation abnormality						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemoglobin decreased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Heart rate increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nuclear magnetic resonance imaging brain abnormal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Protein urine present						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Total lung capacity decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vitamin D increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	5/ 63 (8%)	7/ 64 (11%)	0.7020 (0.2105, 2.3410) /0.565	-3.0010 (-13.1510, 7.1490) /0.562	0.7256 (0.2431, 2.1661) /0.565	0.430
Male	8/220 (4%)	6/219 (3%)	1.3396 (0.4570, 3.9268) /0.594	0.8966 (-2.3886, 4.1819) /0.593	1.3273 (0.4683, 3.7620) /0.594	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cervical dysplasia						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Erectile dysfunction						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	
Breast mass						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital lesion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Prostatitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Breast pain						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysfunctional uterine bleeding						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Menopausal symptoms Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Polymenorrhoea						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Vaginal dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Vaginal ulceration						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vulvar dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
Female	3/ 63 (5%)	3/ 64 (5%)	1.0167 (0.1973, 5.2385) /0.984	0.0744 (-7.3060, 7.4548) /0.984	1.0159 (0.2130, 4.8442) /0.984	0.425
Male	9/220 (4%)	4/219 (2%)	2.2927 (0.6954, 7.5588) /0.173	2.2644 (-0.8973, 5.4261) /0.160	2.2398 (0.7001, 7.1650) /0.174	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.466
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Eosinophilia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.185
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Normocytic anaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Splenomegaly						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	3/ 63 (5%)	2/ 64 (3%)	1.5500 (0.2501, 9.6053) /0.638	1.6369 (-5.1325, 8.4063) /0.636	1.5238 (0.2635, 8.8133) /0.638	0.967
Male	8/220 (4%)	5/219 (2%)	1.6151 (0.5200, 5.0167) /0.407	1.3533 (-1.8141, 4.5206) /0.402	1.5927 (0.5293, 4.7924) /0.408	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	0.195
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	
Haematuria						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Calculus urinary						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Micturition urgency						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nephropathy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Proteinuria Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral caruncle						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Urethral discharge						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Urinary incontinence						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.929
Male	7/220 (3%)	6/219 (3%)	1.1667 (0.3857, 3.5289) /0.785	0.4421 (-2.7286, 3.6128) /0.785	1.1614 (0.3967, 3.4002) /0.785	
Blepharitis						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenopia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Astigmatism						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharospasm						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Conjunctivitis allergic						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye irritation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye pruritus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glare						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lacrimation increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meibomian gland dysfunction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Myopia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uveitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vitreous detachment						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
Female	0/ 63	3/ 64 (5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	0.016
Male	7/220 (3%)	3/219 (1%)	2.3662 (0.6039, 9.2717) /0.216	1.8120 (-0.9717, 4.5957) /0.202	2.3227 (0.6085, 8.8662) /0.218	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain Female	0/ 63	3/ 64 (5%)	<0.0001 (<0.0001, -) />0.999	-6.8715 (-32.6434, 18.9004) /0.601	<0.0001 (<0.0001, -) />0.999	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertigo Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.051
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vertigo positional Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Noninfective myringitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Immune system disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	10/220 (5%)	3/219 (1%)	3.4285 (0.9306, 12.6322) /0.064	3.1756 (0.0219, 6.3293) /0.048	3.3182 (0.9257, 11.8934) /0.066	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	6/220 (3%)	1/219 (<1%)	6.1121 (0.7297, 51.1963) /0.095	2.2707 (-0.0595, 4.6008) /0.056	5.9727 (0.7250, 49.2014) /0.097	
Hypersensitivity						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Mite allergy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.185
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hot flush Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Intermittent claudication						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrioventricular block first degree						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cardiovascular disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Keratosi follicular						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Hypogonadism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis toxic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth extraction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	30/ 63 (48%)	28/ 64 (44%)	1.1688 (0.5811, 2.3510) /0.662	3.8690 (-13.4458, 21.1839) /0.661	1.0884 (0.7445, 1.5913) /0.662	0.060
Male	113/220 (51%)	67/219 (31%)	2.3959 (1.6213, 3.5405) /<.001	20.7700 (11.7774, 29.7626) /<.001	1.6789 (1.3242, 2.1286) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
Female	10/ 63 (16%)	15/ 64 (23%)	0.6164 (0.2532, 1.5001) /0.286	-7.5645 (-21.3170, 6.1880) /0.281	0.6772 (0.3295, 1.3922) /0.289	0.085
Male	46/220 (21%)	33/219 (15%)	1.4901 (0.9105, 2.4386) /0.113	5.8406 (-1.3235, 13.0047) /0.110	1.3876 (0.9245, 2.0827) /0.114	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.290
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.896
Male	5/220 (2%)	4/219 (2%)	1.2500 (0.3312, 4.7183) /0.742	0.4462 (-2.2040, 3.0964) /0.741	1.2443 (0.3386, 4.5722) /0.742	
Influenza						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	3/219 (1%)	1.3333 (0.2949, 6.0283) /0.709	0.4483 (-1.8941, 2.7908) /0.708	1.3273 (0.3006, 5.8611) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.992
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Pharyngitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.102
Male	1/220 (<1%)	4/219 (2%)	0.2454 (0.0272, 2.2136) /0.211	-1.3719 (-3.3557, 0.6118) /0.175	0.2489 (0.0280, 2.2088) /0.212	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Syphilis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	0/ 63	4/ 64 (6%)	<0.0001 (<0.0001, -) />0.999	-8.3654 (-34.2400, 17.5092) /0.526	<0.0001 (<0.0001, -) />0.999	0.006
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Folliculitis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Gonorrhoea						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Herpes simplex						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Furuncle						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.405
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Genital herpes						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Laryngitis Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Ear infection Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Viral infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Cystitis						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis gonococcal						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tracheobronchitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Epididymitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vulvovaginal candidiasis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Onychomycosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Otitis media						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tracheitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Escherichia urinary tract infection						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.097
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Staphylococcal skin infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute hepatitis B						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Eyelid infection Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Genitourinary chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract gonococcal infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Lymphogranulo ma venereum						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaria						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Mycoplasma genitalium infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngeal chlamydia infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pharyngitis streptococcal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Proctitis mycoplasmal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis mycoplasmal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Varicella						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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General disorders and administration site conditions						
Any Event						
Female	15/ 63 (24%)	1/ 64 (2%)	19.6875 (2.5123, 154.2782) /0.005	22.2470 (11.2996, 33.1944) /<.001	15.2381 (2.0744, 111.9362) /0.007	NC
Male	81/220 (37%)	3/219 (1%)	41.9566 (12.9974, 135.4394) /<.001	35.4483 (28.8917, 42.0049) /<.001	26.8773 (8.6212, 83.7924) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	15/ 63 (24%)	0/ 64	>999 (>999, >999) /NC	25.0844 (-1.7265, 51.8952) /0.067	>999 (>999, >999) /NC	NC
Male	77/220 (35%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site induration						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	6/220 (3%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site swelling						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	6/220 (3%)	2/219 (<1%)	3.0421 (0.6072, 15.2402) /0.176	1.8140 (-0.6799, 4.3079) /0.154	2.9864 (0.6094, 14.6346) /0.177	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Influenza like illness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fatigue						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Asthenia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site erythema						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site warmth						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Malaise						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site bruising						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site haematoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Feeling hot						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Catheter site erythema						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Injection site discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	3/ 63 (5%)	2/ 64 (3%)	1.5500 (0.2501, 9.6053) /0.638	1.6369 (-5.1325, 8.4063) /0.636	1.5238 (0.2635, 8.8133) /0.638	0.474
Male	31/220 (14%)	10/219 (5%)	3.4280 (1.6365, 7.1809) /0.001	9.5247 (4.1599, 14.8895) /<.001	3.0859 (1.5512, 6.1389) /0.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.435
Male	11/220 (5%)	4/219 (2%)	2.8289 (0.8867, 9.0251) /0.079	3.1735 (-0.2087, 6.5557) /0.066	2.7375 (0.8852, 8.4657) /0.080	
Nausea						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.473
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Haemorrhoids						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.190
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Toothache						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Constipation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Abdominal pain upper						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Food poisoning						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Gastritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	4/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

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 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Flatulence						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Haemorrhoidal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal distension						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal inflammation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Faeces soft						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Inguinal hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rectal haemorrhage						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Diarrhoea haemorrhagic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Barrett's oesophagus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pancreatitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Paraesthesia oral						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tooth development disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Umbilical hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal and connective tissue disorders						
Any Event						
Female	5/ 63 (8%)	4/ 64 (6%)	1.2931 (0.3308, 5.0554) /0.712	1.6865 (-7.2422, 10.6152) /0.711	1.2698 (0.3573, 4.5124) /0.712	0.657
Male	11/220 (5%)	6/219 (3%)	1.8684 (0.6786, 5.1446) /0.226	2.2603 (-1.3409, 5.8614) /0.219	1.8250 (0.6870, 4.8479) /0.227	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Back pain Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.206
Male	6/220 (3%)	2/219 (<1%)	3.0421 (0.6072, 15.2402) /0.176	1.8140 (-0.6799, 4.3079) /0.154	2.9864 (0.6094, 14.6346) /0.177	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Myalgia Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.302
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Arthralgia Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.190
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Musculoskeletal chest pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondrosis						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Musculoskeletal stiffness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Spinal osteoarthritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoporosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rotator cuff syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	4/ 63 (6%)	4/ 64 (6%)	1.0169 (0.2429, 4.2569) /0.982	0.0992 (-8.3522, 8.5506) /0.982	1.0159 (0.2656, 3.8856) /0.982	0.320
Male	12/220 (5%)	5/219 (2%)	2.4692 (0.8550, 7.1313) /0.095	3.1714 (-0.4227, 6.7656) /0.084	2.3891 (0.8560, 6.6677) /0.096	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	3/ 63 (5%)	1/ 64 (2%)	3.1500 (0.3188, 31.1253) /0.326	3.1994 (-2.8739, 9.2727) /0.302	3.0476 (0.3257, 28.5210) /0.329	0.916
Male	8/220 (4%)	3/219 (1%)	2.7170 (0.7112, 10.3800) /0.144	2.2665 (-0.6470, 5.1800) /0.127	2.6545 (0.7136, 9.8741) /0.145	
Dizziness Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Migraine Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	NC
Amnesia Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Neuropathy peripheral						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anosmia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Cervical neuritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nerve compression						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Radiculitis brachial						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Trigeminal neuralgia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Skin and subcutaneous tissue disorders						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.989
Male	6/220 (3%)	6/219 (3%)	0.9953 (0.3160, 3.1352) /0.994	-0.0125 (-3.0631, 3.0382) /0.994	0.9955 (0.3261, 3.0388) /0.994	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eczema						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rash						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.412
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Erythema						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hyperhidrosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dermatitis atopic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dyshidrotic eczema						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Urticaria						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nail pigmentation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash morbilliform						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	3/ 63 (5%)	2/ 64 (3%)	1.5500 (0.2501, 9.6053) /0.638	1.6369 (-5.1325, 8.4063) /0.636	1.5238 (0.2635, 8.8133) /0.638	0.799
Male	10/220 (5%)	5/219 (2%)	2.0381 (0.6851, 6.0635) /0.201	2.2623 (-1.1273, 5.6520) /0.191	1.9909 (0.6918, 5.7298) /0.202	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.138
Male	5/220 (2%)	2/219 (<1%)	2.5233 (0.4843, 13.1469) /0.272	1.3595 (-0.9784, 3.6973) /0.254	2.4886 (0.4880, 12.6905) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
Female	2/ 63 (3%)	0/ 64	>999 (>999, >999) /NC	5.4180 (-20.1061, 30.9421) /0.677	>999 (>999, >999) /NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rhinitis allergic						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Nasal congestion						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Respiratory disorder Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal turbinate hypertrophy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	3/ 63 (5%)	0/ 64	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.042
Male	8/220 (4%)	9/219 (4%)	0.8805 (0.3334, 2.3257) /0.797	-0.4732 (-4.0831, 3.1366) /0.797	0.8848 (0.3478, 2.2512) /0.797	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.203
Male	2/220 (<1%)	3/219 (1%)	0.6606 (0.1093, 3.9923) /0.651	-0.4608 (-2.4464, 1.5249) /0.649	0.6636 (0.1120, 3.9329) /0.652	
Insomnia Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.272
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	
Libido decreased Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Panic attack						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	>0.999
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Affective disorder						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Major depression						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injury, poisoning and procedural complications						
Any Event						
Female	2/ 63 (3%)	3/ 64 (5%)	0.6667 (0.1076, 4.1313) /0.663	-1.5129 (-8.2627, 5.2369) /0.660	0.6773 (0.1171, 3.9171) /0.663	0.700
Male	9/220 (4%)	9/219 (4%)	0.9953 (0.3874, 2.5567) /0.992	-0.0187 (-3.7286, 3.6912) /0.992	0.9955 (0.4028, 2.4602) /0.992	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Contusion						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.308
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Arthropod sting						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ligament sprain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Wound						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ankle fracture						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Meniscus injury						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure via inhalation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Joint injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Sunburn						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tibia fracture						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.299
Male	3/220 (1%)	6/219 (3%)	0.4908 (0.1212, 1.9877) /0.319	-1.3761 (-4.0261, 1.2739) /0.309	0.4977 (0.1261, 1.9650) /0.319	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.700
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Hypercholesterolaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Type 2 diabetes mellitus						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.094
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gout						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.449
Male	2/220 (<1%)	3/219 (1%)	0.6606 (0.1093, 3.9923) /0.651	-0.4608 (-2.4464, 1.5249) /0.649	0.6636 (0.1120, 3.9329) /0.652	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Lipoma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal neoplasm						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Breast cancer						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Kidney angiomyolipoma						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	2/ 63 (3%)	6/ 64 (9%)	0.3169 (0.0615, 1.6342) /0.170	-6.2004 (-14.5514, 2.1506) /0.146	0.3386 (0.0710, 1.6147) /0.174	0.099
Male	9/220 (4%)	6/219 (3%)	1.5142 (0.5297, 4.3288) /0.439	1.3512 (-2.0437, 4.7460) /0.435	1.4932 (0.5406, 4.1240) /0.439	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	1/ 63 (2%)	2/ 64 (3%)	0.5000 (0.0442, 5.6575) /0.576	-1.5377 (-6.8004, 3.7250) /0.567	0.5079 (0.0472, 5.4615) /0.576	0.088
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
Female	0/ 63	2/ 64 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-31.0629, 20.3226) /0.682	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight decreased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Blood cholesterol increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood folate decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Low density lipoprotein increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma test positive						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Platelet count decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Treponema test positive						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.829
Male	4/220 (2%)	3/219 (1%)	1.3333 (0.2949, 6.0283) /0.709	0.4483 (-1.8941, 2.7908) /0.708	1.3273 (0.3006, 5.8611) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Erectile dysfunction						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Prostatitis Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Ovarian cyst						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Testicular pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.535
Male	1/220 (<1%)	3/219 (1%)	0.3288 (0.0339, 3.1853) /0.337	-0.9153 (-2.6930, 0.8623) /0.313	0.3318 (0.0348, 3.1653) /0.338	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	
Eosinophilia Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypochromic anaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.302
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Proteinuria Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Renal failure Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	
Cataract						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chorioretinal disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic retinopathy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye allergy						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glaucoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ear and labyrinth disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.209
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertension						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	>0.999
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Circulatory collapse						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertensive crisis						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Peripheral ischaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cardiovascular disorder						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Goitre						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperbilirubi naemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic steatosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hydrocholecystis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	2/ 63 (3%)	2/ 64 (3%)	1.0164 (0.1387, 7.4472) /0.987	0.0496 (-6.0261, 6.1253) /0.987	1.0159 (0.1476, 6.9908) /0.987	0.380
Male	21/220 (10%)	8/219 (4%)	2.7833 (1.2051, 6.4280) /0.017	5.8925 (1.2827, 10.5023) /0.012	2.6131 (1.1829, 5.7722) /0.018	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	
Anal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	11/220 (5%)	1/219 (<1%)	11.4737 (1.4684, 89.6530) /0.020	4.5434 (1.5282, 7.5586) /0.003	10.9500 (1.4259, 84.0898) /0.021	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	11/220 (5%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Arthritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Poor quality sleep						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Night sweats						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Suicide attempt						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Multiple injuries						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post lumbar puncture syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal column injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypophosphataemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin cancer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	2/ 63 (3%)	1/ 64 (2%)	2.0656 (0.1826, 23.3721) /0.558	1.6121 (-3.6770, 6.9012) /0.550	2.0317 (0.1890, 21.8459) /0.559	0.619
Male	3/220 (1%)	3/219 (1%)	0.9954 (0.1987, 4.9865) /0.996	-0.0062 (-2.1784, 2.1660) /0.996	0.9955 (0.2031, 4.8782) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipase increased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Alanine aminotransferase increased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Blood triglycerides increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Bile duct stone						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cholecystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatic cirrhosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	0.613
Male	7/220 (3%)	1/219 (<1%)	7.1643 (0.8740, 58.7267) /0.067	2.7252 (0.2400, 5.2104) /0.032	6.9682 (0.8645, 56.1638) /0.068	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Large intestine perforation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Road traffic accident						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Diabetic ketoacidosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Sex at Birth - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight decreased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	77/216 (36%)	79/201 (39%)	0.8555 (0.5751, 1.2724) /0.441	-3.6553 (-12.9500, 5.6393) /0.441	0.9070 (0.7076, 1.1625) /0.441	0.027
Non-White	16/ 67 (24%)	38/ 80 (48%)	0.3467 (0.1700, 0.7072) /0.004	-23.6194 (-38.5850, -8.6538) /0.002	0.5027 (0.3093, 0.8171) /0.006	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	104/216 (48%)	90/201 (45%)	1.1452 (0.7790, 1.6837) /0.490	3.3720 (-6.2018, 12.9459) /0.490	1.0753 (0.8745, 1.3222) /0.491	0.898
Non-White	28/ 67 (42%)	32/ 80 (40%)	1.0769 (0.5565, 2.0839) /0.826	1.7910 (-14.1688, 17.7509) /0.826	1.0448 (0.7076, 1.5427) /0.826	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	42/216 (19%)	35/201 (17%)	1.1448 (0.6969, 1.8808) /0.593	2.0315 (-5.4077, 9.4707) /0.592	1.1167 (0.7445, 1.6748) /0.594	0.919
Non-White	8/ 67 (12%)	9/ 80 (11%)	1.0697 (0.3884, 2.9458) /0.896	0.6903 (-9.7130, 11.0936) /0.897	1.0614 (0.4335, 2.5984) /0.896	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	21/216 (10%)	12/201 (6%)	1.6962 (0.8117, 3.5441) /0.160	3.7521 (-1.3800, 8.8842) /0.152	1.6285 (0.8227, 3.2233) /0.162	0.687
Non-White	11/ 67 (16%)	10/ 80 (13%)	1.3750 (0.5449, 3.4699) /0.500	3.9179 (-7.5363, 15.3721) /0.503	1.3134 (0.5946, 2.9012) /0.500	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	15/216 (7%)	11/201 (5%)	1.2890 (0.5775, 2.8771) /0.535	1.4718 (-3.1520, 6.0956) /0.533	1.2689 (0.5970, 2.6969) /0.536	0.328
Non-White	3/ 67 (4%)	6/ 80 (8%)	0.5781 (0.1389, 2.4055) /0.451	-3.0224 (-10.6274, 4.5826) /0.436	0.5970 (0.1552, 2.2969) /0.453	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
White	12/216 (6%)	7/201 (3%)	1.6303 (0.6288, 4.2265) /0.315	2.0730 (-1.8963, 6.0423) /0.306	1.5952 (0.6407, 3.9716) /0.316	0.435
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	
Pharyngitis						
White	11/216 (5%)	8/201 (4%)	1.2945 (0.5099, 3.2865) /0.587	1.1125 (-2.8749, 5.0999) /0.584	1.2795 (0.5253, 3.1165) /0.587	0.622
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	11/216 (5%)	7/201 (3%)	1.4871 (0.5650, 3.9141) /0.422	1.6100 (-2.2655, 5.4855) /0.416	1.4623 (0.5781, 3.6986) /0.422	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rhinitis						
White	8/216 (4%)	7/201 (3%)	1.0659 (0.3794, 2.9949) /0.904	0.2211 (-3.3520, 3.7942) /0.903	1.0635 (0.3928, 2.8794) /0.904	0.654
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
White	7/216 (3%)	6/201 (3%)	1.0885 (0.3595, 3.2955) /0.881	0.2557 (-3.0777, 3.5890) /0.881	1.0856 (0.3711, 3.1758) /0.881	0.234
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Bronchitis						
White	7/216 (3%)	5/201 (2%)	1.3129 (0.4099, 4.2052) /0.647	0.7532 (-2.4425, 3.9489) /0.644	1.3028 (0.4202, 4.0388) /0.647	0.266
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
White	6/216 (3%)	4/201 (2%)	1.4071 (0.3912, 5.0610) /0.601	0.7877 (-2.1330, 3.7084) /0.597	1.3958 (0.3997, 4.8743) /0.601	0.691
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Respiratory tract infection						
White	4/216 (2%)	7/201 (3%)	0.5229 (0.1507, 1.8139) /0.307	-1.6307 (-4.7382, 1.4768) /0.304	0.5317 (0.1580, 1.7892) /0.308	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
White	6/216 (3%)	4/201 (2%)	1.4071 (0.3912, 5.0610) /0.601	0.7877 (-2.1330, 3.7084) /0.597	1.3958 (0.3997, 4.8743) /0.601	0.229
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
White	3/216 (1%)	5/201 (2%)	0.5521 (0.1302, 2.3407) /0.420	-1.0987 (-3.7579, 1.5606) /0.418	0.5583 (0.1352, 2.3062) /0.421	0.050
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Oral herpes						
White	6/216 (3%)	4/201 (2%)	1.4071 (0.3912, 5.0610) /0.601	0.7877 (-2.1330, 3.7084) /0.597	1.3958 (0.3997, 4.8743) /0.601	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
White	4/216 (2%)	4/201 (2%)	0.9292 (0.2293, 3.7661) /0.918	-0.1382 (-2.7764, 2.5000) /0.918	0.9306 (0.2359, 3.6713) /0.918	0.300
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Conjunctivitis						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.878
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.020
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.101
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth infection						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	0.383
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
White	0/216	6/201 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.056
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Hordeolum						
White	5/216 (2%)	2/201 (<1%)	2.3578 (0.4523, 12.2921) /0.309	1.3198 (-1.1101, 3.7497) /0.287	2.3264 (0.4565, 11.8562) /0.310	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Herpes zoster						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.885
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Pharyngotonsillitis						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	0.172
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Anal chlamydia infection						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.520
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.236
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.031
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Body tinea						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Fungal skin infection						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Subcutaneous abscess						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Genital herpes simplex						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tinea pedis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tooth abscess						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.268
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Tracheobronchitis						
White	0/216	3/201 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
White	0/216	0/201	NC	NC	NC	>0.999
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Anal infection						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanitis candida						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Candida infection						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Epididymitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Otitis externa						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Proctitis chlamydial						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tinea infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Urethritis chlamydial						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Abscess limb						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Acute sinusitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Angular cheilitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anorectal infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vulvovaginitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Bronchitis pneumococcal						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cat scratch disease						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Conjunctivitis bacterial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dacryocystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Fungal infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis shigella						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gastrointestinal infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genitourinary tract infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Groin abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter gastritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Herpes virus infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Infectious colitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Lice infestation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Oophoritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Orchitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Paronychia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pyelonephritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pyelonephritis chronic						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Respiratory tract infection bacterial						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Sexually transmitted disease						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal abscess						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Strongyloidiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinea cruris						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Tonsillitis bacterial						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Upper respiratory tract infection bacterial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Viral tonsillitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	109/216 (50%)	15/201 (7%)	12.6318 (7.0034, 22.7836) /<.001	43.0003 (35.4071, 50.5934) /<.001	6.7620 (4.0833, 11.1981) /<.001	0.646
Non-White	27/ 67 (40%)	6/ 80 (8%)	8.3250 (3.1729, 21.8428) /<.001	32.7985 (19.7121, 45.8849) /<.001	5.3731 (2.3596, 12.2351) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
White	100/216 (46%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	24/ 67 (36%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
White	29/216 (13%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	10/ 67 (15%)	0/ 80	>999 (>999, >999) /NC	16.6303 (-7.1769, 40.4375) /0.171	>999 (>999, >999) /NC	
Injection site induration						
White	29/216 (13%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
White	17/216 (8%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Pyrexia						
White	11/216 (5%)	2/201 (<1%)	5.3390 (1.1686, 24.3919) /0.031	4.0976 (0.8605, 7.3346) /0.013	5.1181 (1.1485, 22.8081) /0.032	0.234
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
White	14/216 (6%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
White	7/216 (3%)	6/201 (3%)	1.0885 (0.3595, 3.2955) /0.881	0.2557 (-3.0777, 3.5890) /0.881	1.0856 (0.3711, 3.1758) /0.881	0.266
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	3/216 (1%)	5/201 (2%)	0.5521 (0.1302, 2.3407) /0.420	-1.0987 (-3.7579, 1.5606) /0.418	0.5583 (0.1352, 2.3062) /0.421	0.534
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	
Asthenia						
White	8/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.110
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Malaise						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.244
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Discomfort						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site haematoma						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nodule						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site haemorrhage						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

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 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Chest discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chest pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site anaesthesia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cyst						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site discolouration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site granuloma						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Injection site necrosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site scar						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Non-cardiac chest pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Swelling						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vessel puncture site bruise						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	56/216 (26%)	37/201 (18%)	1.5513 (0.9707, 2.4794) /0.066	7.5180 (-0.4104, 15.4463) /0.063	1.4084 (0.9747, 2.0352) /0.068	0.061
Non-White	16/ 67 (24%)	25/ 80 (31%)	0.6902 (0.3312, 1.4381) /0.322	-7.3694 (-21.7703, 7.0315) /0.316	0.7642 (0.4467, 1.3074) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	18/216 (8%)	13/201 (6%)	1.3147 (0.6268, 2.7576) /0.469	1.8657 (-3.1490, 6.8803) /0.466	1.2885 (0.6482, 2.5612) /0.470	0.059
Non-White	2/ 67 (3%)	8/ 80 (10%)	0.2769 (0.0567, 1.3517) /0.112	-7.0149 (-14.7493, 0.7194) /0.075	0.2985 (0.0656, 1.3582) /0.118	
Nausea						
White	13/216 (6%)	4/201 (2%)	3.1539 (1.0110, 9.8387) /0.048	4.0285 (0.3154, 7.7416) /0.033	3.0243 (1.0026, 9.1225) /0.049	0.049
Non-White	2/ 67 (3%)	5/ 80 (6%)	0.4615 (0.0866, 2.4594) /0.365	-3.2649 (-9.9537, 3.4239) /0.339	0.4776 (0.0957, 2.3832) /0.368	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.886
Non-White	5/ 67 (7%)	5/ 80 (6%)	1.2097 (0.3348, 4.3701) /0.771	1.2127 (-7.0171, 9.4425) /0.773	1.1940 (0.3610, 3.9498) /0.771	
Haemorrhoids						
White	9/216 (4%)	2/201 (<1%)	4.3261 (0.9233, 20.2700) /0.063	3.1716 (0.1743, 6.1690) /0.038	4.1875 (0.9158, 19.1478) /0.065	0.199
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	0.304
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Toothache						
White	6/216 (3%)	3/201 (1%)	1.8857 (0.4653, 7.6426) /0.374	1.2852 (-1.4739, 4.0444) /0.361	1.8611 (0.4717, 7.3427) /0.375	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	5/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.104
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.116
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.066
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	
Dental caries						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.244
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.066
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Abdominal pain upper						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.162
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.611
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Proctitis						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.162
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gastrooesophageal reflux disease						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Abdominal discomfort						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Dry mouth						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroduodenitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gingival bleeding						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lip dry						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Stomatitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Abdominal distension						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aerophagia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal fistula						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal inflammation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Anal pruritus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Aphthous ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile acid malabsorption						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bowel movement irregularity						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis microscopic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Dysbacterioses						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Enterocolitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Faeces soft						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Gastrointestinal sounds abnormal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Gingival pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Gingival swelling						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Haematochezia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Inguinal hernia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Irritable bowel syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Leukoplakia oral						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lymphoid hyperplasia of intestine						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oesophageal polyp						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Oral pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Palatal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rectal discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal haemorrhage						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tongue eruption						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
White	33/216 (15%)	26/201 (13%)	1.2137 (0.6974, 2.1125) /0.493	2.3425 (-4.3316, 9.0165) /0.492	1.1811 (0.7332, 1.9025) /0.494	0.299
Non-White	13/ 67 (19%)	8/ 80 (10%)	2.1667 (0.8390, 5.5955) /0.110	9.4030 (-2.1243, 20.9303) /0.110	1.9403 (0.8557, 4.3999) /0.113	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	11/216 (5%)	7/201 (3%)	1.4871 (0.5650, 3.9141) /0.422	1.6100 (-2.2655, 5.4855) /0.416	1.4623 (0.5781, 3.6986) /0.422	0.609
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	
Myalgia						
White	8/216 (4%)	4/201 (2%)	1.8942 (0.5615, 6.3901) /0.303	1.7137 (-1.4598, 4.8871) /0.290	1.8611 (0.5692, 6.0856) /0.304	0.069
Non-White	4/ 67 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	4/216 (2%)	4/201 (2%)	0.9292 (0.2293, 3.7661) /0.918	-0.1382 (-2.7764, 2.5000) /0.918	0.9306 (0.2359, 3.6713) /0.918	0.837
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	
Muscle contracture						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.385
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Muscle spasms						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.520
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Neck pain						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.900
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Musculoskeletal discomfort						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondrosis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Plantar fasciitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal disorder						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bursitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Intervertebral disc disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Joint swelling						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Musculoskeletal stiffness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

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Osteoarthritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Osteonecrosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

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 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue mass						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Spinal osteoarthritis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	37/216 (17%)	15/201 (7%)	2.5631 (1.3596, 4.8321) /0.004	9.6669 (3.4666, 15.8673) /0.002	2.2954 (1.3002, 4.0521) /0.004	0.290
Non-White	10/ 67 (15%)	9/ 80 (11%)	1.3840 (0.5269, 3.6351) /0.509	3.6754 (-7.3131, 14.6638) /0.512	1.3267 (0.5727, 3.0732) /0.510	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
White	23/216 (11%)	10/201 (5%)	2.2762 (1.0551, 4.9105) /0.036	5.6730 (0.5783, 10.7677) /0.029	2.1403 (1.0448, 4.3844) /0.038	0.164
Non-White	5/ 67 (7%)	7/ 80 (9%)	0.8410 (0.2542, 2.7826) /0.777	-1.2873 (-10.1153, 7.5407) /0.775	0.8529 (0.2837, 2.5642) /0.777	
Dizziness						
White	9/216 (4%)	2/201 (<1%)	4.3261 (0.9233, 20.2700) /0.063	3.1716 (0.1743, 6.1690) /0.038	4.1875 (0.9158, 19.1478) /0.065	0.922
Non-White	4/ 67 (6%)	1/ 80 (1%)	5.0159 (0.5469, 46.0064) /0.154	4.7201 (-1.4535, 10.8938) /0.134	4.7761 (0.5469, 41.7109) /0.157	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Sciatica						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Migraine						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Somnolence						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Amnesia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Disturbance in attention						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypoaesthesia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Poor quality sleep						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tension headache						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tremor						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Visual field defect						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	30/216 (14%)	18/201 (9%)	1.6398 (0.8830, 3.0451) /0.117	4.9337 (-1.1370, 11.0043) /0.111	1.5509 (0.8931, 2.6932) /0.119	0.985
Non-White	9/ 67 (13%)	7/ 80 (9%)	1.6182 (0.5685, 4.6066) /0.367	4.6828 (-5.5647, 14.9303) /0.370	1.5352 (0.6040, 3.9021) /0.368	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
White	6/216 (3%)	2/201 (<1%)	2.8429 (0.5671, 14.2509) /0.204	1.7828 (-0.8029, 4.3684) /0.177	2.7917 (0.5700, 13.6723) /0.205	0.135
Non-White	1/ 67 (1%)	3/ 80 (4%)	0.3889 (0.0395, 3.8285) /0.418	-2.2575 (-7.3330, 2.8181) /0.383	0.3980 (0.0424, 3.7378) /0.420	
Rash						
White	2/216 (<1%)	4/201 (2%)	0.4603 (0.0834, 2.5407) /0.373	-1.0641 (-3.3791, 1.2509) /0.368	0.4653 (0.0862, 2.5127) /0.374	0.128
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.611
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Seborrhoeic dermatitis						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin lesion						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Erythema						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

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Hyperhidrosis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Intertrigo						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Papule						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Pityriasis						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Pruritus generalised						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash pruritic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Skin mass						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Alopecia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Dermatitis allergic						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dyshidrotic eczema						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ephelides						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Granuloma annulare						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipodystrophy acquired						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Night sweats						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile ulceration						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pityriasis alba						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Psoriasis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash generalised						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash maculo-papular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash vesicular						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin erosion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin hyperpigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypopigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Skin induration						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin reaction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Xeroderma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Respiratory, thoracic and mediastinal disorders						
Any Event						
White	25/216 (12%)	18/201 (9%)	1.3307 (0.7025, 2.5209) /0.381	2.6189 (-3.1935, 8.4312) /0.377	1.2924 (0.7275, 2.2959) /0.382	0.155
Non-White	4/ 67 (6%)	9/ 80 (11%)	0.5009 (0.1470, 1.7062) /0.269	-5.2799 (-14.2314, 3.6717) /0.248	0.5307 (0.1711, 1.6464) /0.273	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Cough						
White	3/216 (1%)	5/201 (2%)	0.5521 (0.1302, 2.3407) /0.420	-1.0987 (-3.7579, 1.5606) /0.418	0.5583 (0.1352, 2.3062) /0.421	0.952
Non-White	2/ 67 (3%)	4/ 80 (5%)	0.5846 (0.1037, 3.2956) /0.543	-2.0149 (-8.2929, 4.2630) /0.529	0.5970 (0.1128, 3.1590) /0.544	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oropharyngeal pain						
White	7/216 (3%)	3/201 (1%)	2.2105 (0.5637, 8.6679) /0.255	1.7482 (-1.1478, 4.6442) /0.237	2.1713 (0.5692, 8.2823) /0.256	0.703
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Rhinitis allergic						
White	6/216 (3%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.088
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Catarrh						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nasal congestion						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.520
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
White	0/216	5/201 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Asthma						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Epistaxis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Productive cough						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Bronchial obstruction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis chronic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bronchospasm						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nasal obstruction						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Reflux laryngitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tonsillar hypertrophy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Wheezing						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	18/216 (8%)	13/201 (6%)	1.3147 (0.6268, 2.7576) /0.469	1.8657 (-3.1490, 6.8803) /0.466	1.2885 (0.6482, 2.5612) /0.470	0.360
Non-White	8/ 67 (12%)	4/ 80 (5%)	2.5763 (0.7400, 8.9694) /0.137	6.9403 (-2.1753, 16.0559) /0.136	2.3881 (0.7520, 7.5836) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
White	7/216 (3%)	3/201 (1%)	2.2105 (0.5637, 8.6679) /0.255	1.7482 (-1.1478, 4.6442) /0.237	2.1713 (0.5692, 8.2823) /0.256	0.212
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Insomnia						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.878
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
White	4/216 (2%)	1/201 (<1%)	3.7736 (0.4182, 34.0501) /0.237	1.3543 (-0.6898, 3.3985) /0.194	3.7222 (0.4196, 33.0226) /0.238	0.482
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Depression						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.317
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Libido decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.345
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Adjustment disorder						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nervousness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Nightmare						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

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Stress						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Suicidal ideation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Acute stress disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Affect lability						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anxiety disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Intentional self-injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Paranoia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injury, poisoning and procedural complications						
Any Event						
White	14/216 (6%)	15/201 (7%)	0.8594 (0.4039, 1.8286) /0.694	-0.9812 (-5.8779, 3.9155) /0.695	0.8685 (0.4302, 1.7535) /0.694	0.583
Non-White	4/ 67 (6%)	8/ 80 (10%)	0.5714 (0.1642, 1.9884) /0.379	-4.0299 (-12.7133, 4.6536) /0.363	0.5970 (0.1880, 1.8959) /0.382	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.254
Non-White	0/ 67	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-32.0243, 17.6830) /0.572	<0.0001 (<0.0001, -) />0.999	
Contusion						
White	5/216 (2%)	1/201 (<1%)	4.7393 (0.5489, 40.9203) /0.157	1.8173 (-0.4115, 4.0461) /0.110	4.6528 (0.5483, 39.4836) /0.159	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Thermal burn						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Muscle strain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Procedural pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin abrasion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Bone contusion						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Craniocerebral injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Epicondylitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Foot fracture						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Heat stroke						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Ligament sprain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Multiple injuries						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Penile contusion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Traumatic haematoma						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral injury						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Wound						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Metabolism and nutrition disorders						
Any Event						
White	19/216 (9%)	10/201 (5%)	1.8421 (0.8351, 4.0637) /0.130	3.8212 (-1.0061, 8.6485) /0.121	1.7681 (0.8425, 3.7103) /0.132	0.934
Non-White	7/ 67 (10%)	5/ 80 (6%)	1.7500 (0.5288, 5.7916) /0.359	4.1978 (-4.8455, 13.2410) /0.363	1.6716 (0.5560, 5.0258) /0.360	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

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Vitamin D deficiency						
White	14/216 (6%)	7/201 (3%)	1.9208 (0.7590, 4.8606) /0.168	2.9989 (-1.1489, 7.1467) /0.156	1.8611 (0.7668, 4.5172) /0.170	0.614
Non-White	7/ 67 (10%)	3/ 80 (4%)	2.9944 (0.7429, 12.0701) /0.123	6.6978 (-1.7269, 15.1225) /0.119	2.7861 (0.7495, 10.3564) /0.126	
Hypovitaminosis						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Hypertriglyceridaemia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glucose tolerance impaired						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperlipasaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypocalcaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypokalaemia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypomagnesaemia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hypophosphataemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Iron deficiency						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Type 2 diabetes mellitus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	13/216 (6%)	13/201 (6%)	0.9261 (0.4187, 2.0487) /0.850	-0.4491 (-5.0990, 4.2007) /0.850	0.9306 (0.4420, 1.9589) /0.850	0.298
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	8/216 (4%)	3/201 (1%)	2.5385 (0.6640, 9.7051) /0.173	2.2112 (-0.8142, 5.2365) /0.152	2.4815 (0.6676, 9.2237) /0.175	0.779
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	
Skin papilloma						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Melanocytic naevus White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral papilloma						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Uterine leiomyoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign spleen tumour						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Dysplastic naevus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Neoplasm skin						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral fibroma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Investigations						
Any Event						
White	17/216 (8%)	8/201 (4%)	2.0609 (0.8692, 4.8866) /0.101	3.8903 (-0.6041, 8.3846) /0.090	1.9774 (0.8726, 4.4811) /0.102	0.577
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Blood creatine phosphokinase increased						
White	2/216 (<1%)	4/201 (2%)	0.4603 (0.0834, 2.5407) /0.373	-1.0641 (-3.3791, 1.2509) /0.368	0.4653 (0.0862, 2.5127) /0.374	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lipase increased						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Vitamin D decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.345
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Blood glucose abnormal						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

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 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Carbon dioxide decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Creatinine renal clearance decreased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Electrocardiogram QT prolonged						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Haemoglobin decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heart rate increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nuclear magnetic resonance imaging brain abnormal						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Protein urine present						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Total lung capacity decreased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Weight increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	11/216 (5%)	8/201 (4%)	1.2945 (0.5099, 3.2865) /0.587	1.1125 (-2.8749, 5.0999) /0.584	1.2795 (0.5253, 3.1165) /0.587	0.275
Non-White	2/ 67 (3%)	5/ 80 (6%)	0.4615 (0.0866, 2.4594) /0.365	-3.2649 (-9.9537, 3.4239) /0.339	0.4776 (0.0957, 2.3832) /0.368	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
White	5/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Breast mass						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital lesion						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Prostatitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Breast pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dysfunctional uterine bleeding						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Menopausal symptoms						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Polymenorrhoea						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Vaginal dysplasia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal haemorrhage						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vaginal ulceration						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Varicocele						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vulvar dysplasia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vulvovaginal pruritus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
White	11/216 (5%)	5/201 (2%)	2.1034 (0.7178, 6.1636) /0.175	2.6050 (-1.0325, 6.2426) /0.160	2.0472 (0.7239, 5.7893) /0.177	0.720
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	4/216 (2%)	2/201 (<1%)	1.8774 (0.3401, 10.3629) /0.470	0.8568 (-1.4049, 3.1185) /0.458	1.8611 (0.3446, 10.0508) /0.470	0.344
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Eosinophilia						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Leukocytosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Normocytic anaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Splenomegaly						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	8/216 (4%)	5/201 (2%)	1.5077 (0.4850, 4.6872) /0.478	1.2161 (-2.0973, 4.5296) /0.472	1.4889 (0.4953, 4.4761) /0.478	0.861
Non-White	3/ 67 (4%)	2/ 80 (3%)	1.8281 (0.2964, 11.2770) /0.516	1.9776 (-4.0413, 7.9965) /0.520	1.7910 (0.3083, 10.4052) /0.516	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.161
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Haematuria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Calculus urinary						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Micturition urgency						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nephropathy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Proteinuria						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral caruncle						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Urethral discharge						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Urinary incontinence						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
White	7/216 (3%)	3/201 (1%)	2.2105 (0.5637, 8.6679) /0.255	1.7482 (-1.1478, 4.6442) /0.237	2.1713 (0.5692, 8.2823) /0.256	0.094
Non-White	1/ 67 (1%)	4/ 80 (5%)	0.2879 (0.0314, 2.6400) /0.271	-3.5075 (-9.0966, 2.0817) /0.219	0.2985 (0.0342, 2.6069) /0.274	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Asthenopia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Blepharospasm						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Dry eye						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye irritation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Eye pain						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Glare						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Meibomian gland dysfunction						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Uveitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	7/216 (3%)	5/201 (2%)	1.3129 (0.4099, 4.2052) /0.647	0.7532 (-2.4425, 3.9489) /0.644	1.3028 (0.4202, 4.0388) /0.647	0.237
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.452
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Vertigo						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cerumen impaction						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hypoacusis						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Deafness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective myringitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tinnitus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	7/216 (3%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.025
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.306
Non-White	3/ 67 (4%)	1/ 80 (1%)	3.7031 (0.3761, 36.4604) /0.262	3.2276 (-2.2906, 8.7458) /0.252	3.5821 (0.3814, 33.6402) /0.264	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.111
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Mite allergy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypertension						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intermittent claudication						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Peripheral venous disease						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrioventricular block first degree						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Cardiovascular disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Keratosis follicular						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypogonadism						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypothyroidism						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatobiliary disorders						
Any Event						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cholelithiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatitis toxic						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tooth extraction						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	101/216 (47%)	67/201 (33%)	1.7565 (1.1812, 2.6120) /0.005	13.4259 (4.1122, 22.7396) /0.005	1.4028 (1.1015, 1.7865) /0.006	0.257
Non-White	42/ 67 (63%)	28/ 80 (35%)	3.1200 (1.5879, 6.1304) /<.001	27.6866 (12.0868, 43.2863) /<.001	1.7910 (1.2607, 2.5445) /0.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	37/216 (17%)	35/201 (17%)	0.9804 (0.5898, 1.6295) /0.939	-0.2833 (-7.5449, 6.9782) /0.939	0.9837 (0.6461, 1.4977) /0.939	0.133
Non-White	19/ 67 (28%)	13/ 80 (16%)	2.0401 (0.9195, 4.5262) /0.080	12.1082 (-1.3764, 25.5928) /0.078	1.7451 (0.9328, 3.2647) /0.081	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	4/216 (2%)	2/201 (<1%)	1.8774 (0.3401, 10.3629) /0.470	0.8568 (-1.4049, 3.1185) /0.458	1.8611 (0.3446, 10.0508) /0.470	0.734
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	4/216 (2%)	4/201 (2%)	0.9292 (0.2293, 3.7661) /0.918	-0.1382 (-2.7764, 2.5000) /0.918	0.9306 (0.2359, 3.6713) /0.918	0.492
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	0.069
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	0.157
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Pharyngitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	2/216 (<1%)	4/201 (2%)	0.4603 (0.0834, 2.5407) /0.373	-1.0641 (-3.3791, 1.2509) /0.368	0.4653 (0.0862, 2.5127) /0.374	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rhinitis						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Bronchitis						
White	4/216 (2%)	3/201 (1%)	1.2453 (0.2753, 5.6338) /0.776	0.3593 (-2.0988, 2.8174) /0.774	1.2407 (0.2812, 5.4755) /0.776	0.121
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Folliculitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Respiratory tract infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gonorrhoea						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.157
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
White	0/216	0/201	NC	NC	NC	NC
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Herpes simplex						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Furuncle						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Tooth infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.157
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Genital herpes						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Laryngitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal chlamydia infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
White	0/216	3/201 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Ear infection						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Viral infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Cystitis						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Proctitis gonococcal						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.900
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tooth abscess						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tracheobronchitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.900
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Epididymitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vulvovaginal candidiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Onychomycosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Otitis media						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Tracheitis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pneumonia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	
Abscess						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Erysipelas						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genital candidiasis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary chlamydia infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Genitourinary tract gonococcal infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatitis E						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranulo ma venereum						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Malaria						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma genitalium infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Pharyngeal chlamydia infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Post procedural infection						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Urethritis mycoplasmal						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Varicella						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vulvovaginal mycotic infection						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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General disorders and administration site conditions						
Any Event						
White	73/216 (34%)	4/201 (2%)	25.1416 (8.9825, 70.3703) /<.001	31.8062 (25.2093, 38.4032) /<.001	16.9826 (6.3232, 45.6117) /<.001	NC
Non-White	23/ 67 (34%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
White	71/216 (33%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	21/ 67 (31%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site nodule						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site induration						
White	7/216 (3%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Injection site swelling						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	4/216 (2%)	2/201 (<1%)	1.8774 (0.3401, 10.3629) /0.470	0.8568 (-1.4049, 3.1185) /0.458	1.8611 (0.3446, 10.0508) /0.470	0.201
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Influenza like illness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Asthenia						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site erythema						
White	0/216	0/201	NC	NC	NC	NC
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	
Injection site warmth						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Malaise						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Injection site bruising						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site haematoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

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 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Chest pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Injection site discolouration						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

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Feeling hot						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Catheter site erythema						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site discomfort						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
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Gastrointestinal disorders						
Any Event						
White	24/216 (11%)	8/201 (4%)	3.0156 (1.3219, 6.8793) /0.009	7.1310 (2.1441, 12.1179) /0.005	2.7917 (1.2839, 6.0702) /0.010	0.923
Non-White	10/ 67 (15%)	4/ 80 (5%)	3.3333 (0.9947, 11.1707) /0.051	9.9254 (0.1473, 19.7035) /0.047	2.9851 (0.9806, 9.0866) /0.054	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Diarrhoea						
White	8/216 (4%)	3/201 (1%)	2.5385 (0.6640, 9.7051) /0.173	2.2112 (-0.8142, 5.2365) /0.152	2.4815 (0.6676, 9.2237) /0.175	0.602
Non-White	4/ 67 (6%)	1/ 80 (1%)	5.0159 (0.5469, 46.0064) /0.154	4.7201 (-1.4535, 10.8938) /0.134	4.7761 (0.5469, 41.7109) /0.157	
Nausea						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.268
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.317
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Haemorrhoids						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.221
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Toothache						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Constipation						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain upper						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Food poisoning						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Proctitis						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal fissure						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal haemorrhage						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Abdominal distension						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal inflammation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Faeces soft						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rectal haemorrhage						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea haemorrhagic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Barrett's oesophagus						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Paraesthesia oral						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tooth development disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Umbilical hernia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal and connective tissue disorders						
Any Event						
White	13/216 (6%)	7/201 (3%)	1.7748 (0.6935, 4.5420) /0.231	2.5359 (-1.5241, 6.5959) /0.221	1.7282 (0.7036, 4.2444) /0.233	0.688
Non-White	3/ 67 (4%)	3/ 80 (4%)	1.2031 (0.2347, 6.1669) /0.824	0.7276 (-5.7419, 7.1971) /0.826	1.1940 (0.2491, 5.7223) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Back pain						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	0.758
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Myalgia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Arthralgia						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.221
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Muscle spasms						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal chest pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Pain in extremity						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Neck pain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Osteochondrosis						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Osteoarthritis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Osteoporosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Temporomandibular joint syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	11/216 (5%)	6/201 (3%)	1.7439 (0.6327, 4.8066) /0.282	2.1075 (-1.6515, 5.8666) /0.272	1.7060 (0.6429, 4.5274) /0.283	0.859
Non-White	5/ 67 (7%)	3/ 80 (4%)	2.0699 (0.4760, 9.0016) /0.332	3.7127 (-3.8322, 11.2576) /0.335	1.9900 (0.4937, 8.0223) /0.333	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
White	8/216 (4%)	2/201 (<1%)	3.8269 (0.8029, 18.2413) /0.092	2.7087 (-0.1594, 5.5767) /0.064	3.7222 (0.7999, 17.3199) /0.094	0.539
Non-White	3/ 67 (4%)	2/ 80 (3%)	1.8281 (0.2964, 11.2770) /0.516	1.9776 (-4.0413, 7.9965) /0.520	1.7910 (0.3083, 10.4052) /0.516	
Dizziness						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Migraine						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Amnesia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Neuropathy peripheral						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anosmia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical neuritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nerve compression						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Trigeminal neuralgia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	3/216 (1%)	5/201 (2%)	0.5521 (0.1302, 2.3407) /0.420	-1.0987 (-3.7579, 1.5606) /0.418	0.5583 (0.1352, 2.3062) /0.421	0.181
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Rash						
White	0/216	3/201 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Erythema						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperhidrosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dermatitis atopic						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Dyshidrotic eczema						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rash vesicular						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Urticaria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dandruff						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nail pigmentation						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rash morbilliform						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	8/216 (4%)	5/201 (2%)	1.5077 (0.4850, 4.6872) /0.478	1.2161 (-2.0973, 4.5296) /0.472	1.4889 (0.4953, 4.4761) /0.478	0.476
Non-White	5/ 67 (7%)	2/ 80 (3%)	3.1452 (0.5901, 16.7643) /0.180	4.9627 (-2.1996, 12.1250) /0.174	2.9851 (0.5982, 14.8947) /0.182	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	3/216 (1%)	3/201 (1%)	0.9296 (0.1854, 4.6596) /0.929	-0.1036 (-2.3940, 2.1867) /0.929	0.9306 (0.1900, 4.5574) /0.929	0.101
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Catarrh						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
White	0/216	0/201	NC	NC	NC	>0.999
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Asthma						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nasal turbinate hypertrophy						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	8/216 (4%)	4/201 (2%)	1.8942 (0.5615, 6.3901) /0.303	1.7137 (-1.4598, 4.8871) /0.290	1.8611 (0.5692, 6.0856) /0.304	0.297
Non-White	3/ 67 (4%)	5/ 80 (6%)	0.7031 (0.1617, 3.0571) /0.639	-1.7724 (-9.0290, 5.4842) /0.632	0.7164 (0.1777, 2.8880) /0.639	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	0.244
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Insomnia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.811
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	
Libido decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Panic attack						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Affective disorder						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Drug abuse						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Major depression						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Injury, poisoning and procedural complications						
Any Event						
White	10/216 (5%)	11/201 (5%)	0.8385 (0.3482, 2.0190) /0.694	-0.8430 (-5.0548, 3.3688) /0.695	0.8460 (0.3672, 1.9489) /0.694	0.815
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Arthropod bite						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Contusion						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.061
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Laceration						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Arthropod sting						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Fall						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Ligament sprain						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Limb injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Wound						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ankle fracture						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Meniscus injury						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Exposure via inhalation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Joint injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Sunburn						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Tibia fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	1/216 (<1%)	5/201 (2%)	0.1823 (0.0211, 1.5743) /0.122	-2.0246 (-4.3603, 0.3111) /0.089	0.1861 (0.0219, 1.5793) /0.123	0.041
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.811
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hypophosphataemia						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.081
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetes mellitus						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Gout						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	4/216 (2%)	4/201 (2%)	0.9292 (0.2293, 3.7661) /0.918	-0.1382 (-2.7764, 2.5000) /0.918	0.9306 (0.2359, 3.6713) /0.918	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lipoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal neoplasm						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Breast cancer						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Kidney angiomyolipoma						
a White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Investigations						
Any Event						
White	6/216 (3%)	8/201 (4%)	0.6893 (0.2349, 2.0224) /0.498	-1.2023 (-4.6818, 2.2772) /0.498	0.6979 (0.2465, 1.9764) /0.498	0.363
Non-White	5/ 67 (7%)	4/ 80 (5%)	1.5323 (0.3945, 5.9515) /0.538	2.4627 (-5.4369, 10.3622) /0.541	1.4925 (0.4174, 5.3365) /0.538	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Blood creatine phosphokinase increased						
White	3/216 (1%)	2/201 (<1%)	1.4014 (0.2317, 8.4746) /0.713	0.3939 (-1.6842, 2.4720) /0.710	1.3958 (0.2357, 8.2676) /0.713	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.236
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glomerular filtration rate decreased						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Weight decreased						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Blood cholesterol increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood folate decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Low density lipoprotein increased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma test positive						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Platelet count decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Treponema test positive						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	3/216 (1%)	5/201 (2%)	0.5521 (0.1302, 2.3407) /0.420	-1.0987 (-3.7579, 1.5606) /0.418	0.5583 (0.1352, 2.3062) /0.421	0.020
Non-White	3/ 67 (4%)	0/ 80	>999 (>999, >999) /NC	6.6704 (-16.3851, 29.7260) /0.571	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Erectile dysfunction						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Prostatitis White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstruation irregular						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Ovarian cyst						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Testicular pain						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
White	1/216 (<1%)	3/201 (1%)	0.3070 (0.0317, 2.9755) /0.308	-1.0296 (-2.9347, 0.8755) /0.290	0.3102 (0.0325, 2.9577) /0.309	0.455
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Eosinophilia						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Hypochromic anaemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Proteinuria						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Renal failure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.433
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Cataract						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Chorioretinal disorder						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic retinopathy						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Eye allergy						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glaucoma						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.244
Non-White	2/ 67 (3%)	1/ 80 (1%)	2.4308 (0.2155, 27.4125) /0.472	1.7351 (-3.0116, 6.4818) /0.474	2.3881 (0.2214, 25.7618) /0.473	
Hypertension						
White	0/216	0/201	NC	NC	NC	>0.999
Non-White	1/ 67 (1%)	1/ 80 (1%)	1.1970 (0.0734, 19.5076) /0.900	0.2425 (-3.5465, 4.0316) /0.900	1.1940 (0.0761, 18.7290) /0.900	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Circulatory collapse						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hypertensive crisis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Peripheral ischaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Goitre						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hyperbilirubi naemia						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic steatosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hydrocholecystis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	21/216 (10%)	8/201 (4%)	2.5981 (1.1235, 6.0077) /0.026	5.7421 (0.9553, 10.5289) /0.019	2.4427 (1.1071, 5.3894) /0.027	0.504
Non-White	2/ 67 (3%)	2/ 80 (3%)	1.2000 (0.1645, 8.7560) /0.857	0.4851 (-4.8355, 5.8057) /0.858	1.1940 (0.1728, 8.2502) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Anal abscess						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatitis A						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	9/216 (4%)	1/201 (<1%)	8.6956 (1.0917, 69.2629) /0.041	3.6692 (0.8323, 6.5060) /0.011	8.3750 (1.0706, 65.5153) /0.043	0.491
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	
Injection site induration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Colitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Arthritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Poor quality sleep						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Night sweats						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Multiple injuries						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Post lumbar puncture syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hypophosphataemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adenocarcinoma of colon						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin cancer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	5/216 (2%)	3/201 (1%)	1.5640 (0.3689, 6.6304) /0.544	0.8223 (-1.7914, 3.4360) /0.537	1.5509 (0.3755, 6.4062) /0.544	0.217
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.345
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Alanine aminotransferase increased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Blood triglycerides increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
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 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bile duct stone						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cholecystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatic cirrhosis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	6/216 (3%)	1/201 (<1%)	5.7142 (0.6819, 47.8846) /0.108	2.2803 (-0.1174, 4.6780) /0.062	5.5833 (0.6781, 45.9731) /0.110	0.416
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Large intestine perforation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Road traffic accident						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Lipase increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Race - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Weight decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	12/ 47 (26%)	16/ 62 (26%)	0.9857 (0.4138, 2.3482) /0.974	-0.2745 (-16.8284, 16.2794) /0.974	0.9894 (0.5189, 1.8864) /0.974	0.321
Europe	76/213 (36%)	89/192 (46%)	0.6420 (0.4309, 0.9566) /0.029	-10.6734 (-20.2203, -1.1265) /0.028	0.7697 (0.6080, 0.9746) /0.030	
Rest of World	5/ 23 (22%)	14/ 29 (48%)	0.2976 (0.0870, 1.0179) /0.053	-26.5367 (-51.3343, -1.7391) /0.036	0.4503 (0.1902, 1.0664) /0.070	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Infections and infestations						
Any Event						
North America	19/ 47 (40%)	21/ 62 (34%)	1.3248 (0.6044, 2.9041) /0.482	6.5546 (-11.7654, 24.8745) /0.483	1.1935 (0.7302, 1.9508) /0.480	0.863
Europe	102/213 (48%)	88/192 (46%)	1.0860 (0.7346, 1.6056) /0.679	2.0540 (-7.6763, 11.7843) /0.679	1.0448 (0.8486, 1.2864) /0.680	
Rest of World	11/ 23 (48%)	14/ 29 (48%)	0.9821 (0.3284, 2.9369) /0.974	-0.4498 (-27.7907, 26.8912) /0.974	0.9907 (0.5606, 1.7506) /0.974	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	1/ 47 (2%)	6/ 62 (10%)	0.2029 (0.0236, 1.7464) /0.146	-7.5498 (-15.9865, 0.8869) /0.079	0.2199 (0.0274, 1.7648) /0.154	0.177
Europe	46/213 (22%)	35/192 (18%)	1.2356 (0.7565, 2.0182) /0.398	3.3671 (-4.4022, 11.1363) /0.396	1.1847 (0.7989, 1.7568) /0.399	
Rest of World	3/ 23 (13%)	3/ 29 (10%)	1.3000 (0.2367, 7.1387) /0.763	2.6987 (-14.9732, 20.3705) /0.765	1.2609 (0.2803, 5.6725) /0.763	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	10/ 47 (21%)	15/ 62 (24%)	0.8468 (0.3413, 2.1012) /0.720	-2.9170 (-18.7452, 12.9113) /0.718	0.8794 (0.4347, 1.7792) /0.721	0.017
Europe	15/213 (7%)	2/192 (1%)	7.1970 (1.6240, 31.8945) /0.009	6.0006 (2.2765, 9.7247) /0.002	6.7606 (1.5662, 29.1824) /0.010	
Rest of World	7/ 23 (30%)	6/ 29 (21%)	1.6771 (0.4741, 5.9325) /0.422	9.7451 (-14.1500, 33.6402) /0.424	1.4710 (0.5728, 3.7777) /0.423	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.410
Europe	15/213 (7%)	11/192 (6%)	1.2466 (0.5580, 2.7846) /0.591	1.3131 (-3.4421, 6.0683) /0.588	1.2292 (0.5788, 2.6105) /0.591	
Rest of World	1/ 23 (4%)	4/ 29 (14%)	0.2841 (0.0295, 2.7360) /0.276	-9.4453 (-24.5107, 5.6202) /0.219	0.3152 (0.0378, 2.6310) /0.286	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
North America	0/ 47	0/ 62	NC	NC	NC	0.770
Europe	12/213 (6%)	7/192 (4%)	1.5778 (0.6082, 4.0933) /0.348	1.9880 (-2.0884, 6.0643) /0.339	1.5453 (0.6211, 3.8448) /0.349	
Rest of World	1/ 23 (4%)	2/ 29 (7%)	0.6136 (0.0521, 7.2227) /0.698	-2.5487 (-14.9791, 9.8817) /0.688	0.6304 (0.0609, 6.5267) /0.699	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
North America	0/ 47	0/ 62	NC	NC	NC	0.850
Europe	11/213 (5%)	8/192 (4%)	1.2525 (0.4930, 3.1819) /0.636	0.9977 (-3.1038, 5.0991) /0.634	1.2394 (0.5092, 3.0169) /0.636	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	11/213 (5%)	7/192 (4%)	1.4392 (0.5464, 3.7904) /0.461	1.5185 (-2.4641, 5.5011) /0.455	1.4165 (0.5604, 3.5806) /0.462	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	0.149
Europe	9/213 (4%)	6/192 (3%)	1.3676 (0.4777, 3.9158) /0.560	1.1004 (-2.5542, 4.7549) /0.555	1.3521 (0.4903, 3.7288) /0.560	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	8/213 (4%)	6/192 (3%)	1.2098 (0.4121, 3.5515) /0.729	0.6309 (-2.9154, 4.1772) /0.727	1.2019 (0.4246, 3.4016) /0.729	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	6/213 (3%)	5/192 (3%)	1.0841 (0.3255, 3.6107) /0.895	0.2127 (-2.9514, 3.3769) /0.895	1.0817 (0.3355, 3.4876) /0.895	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.967
Europe	6/213 (3%)	3/192 (2%)	1.8261 (0.4504, 7.4041) /0.399	1.2544 (-1.5766, 4.0854) /0.385	1.8028 (0.4571, 7.1097) /0.400	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	7/192 (4%)	0.5058 (0.1457, 1.7554) /0.283	-1.7679 (-4.9853, 1.4495) /0.281	0.5151 (0.1532, 1.7323) /0.284	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	6/213 (3%)	4/192 (2%)	1.3623 (0.3786, 4.9021) /0.636	0.7336 (-2.2695, 3.7367) /0.632	1.3521 (0.3874, 4.7195) /0.636	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	5/192 (3%)	0.8990 (0.2562, 3.1544) /0.868	-0.2567 (-3.2914, 2.7779) /0.868	0.9014 (0.2650, 3.0659) /0.868	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.997
Europe	5/213 (2%)	3/192 (2%)	1.5144 (0.3571, 6.4229) /0.573	0.7849 (-1.9005, 3.4703) /0.567	1.5023 (0.3639, 6.2030) /0.574	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	4/192 (2%)	0.8995 (0.2219, 3.6471) /0.882	-0.2054 (-2.9266, 2.5158) /0.882	0.9014 (0.2286, 3.5549) /0.882	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	3/192 (2%)	1.5144 (0.3571, 6.4229) /0.573	0.7849 (-1.9005, 3.4703) /0.567	1.5023 (0.3639, 6.2030) /0.574	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Furuncle North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.323
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.318
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Papilloma viral infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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-----	-----	-----	-----	-----	-----	-----
Tooth infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	6/213 (3%)	2/192 (1%)	2.7536 (0.5491, 13.8086) /0.218	1.7752 (-0.8704, 4.4209) /0.188	2.7042 (0.5524, 13.2393) /0.220	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urinary tract infection						
North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	5/192 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hordeolum North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Genital herpes						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Herpes zoster						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.246
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	3/192 (2%)	0.5972 (0.0987, 3.6123) /0.575	-0.6235 (-2.8041, 1.5570) /0.575	0.6009 (0.1015, 3.5583) /0.575	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.986
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.336
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	3/192 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanitis candida						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Otitis externa						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Proctitis chlamydial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tinea infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urethritis chlamydial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal candidiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Abscess limb North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acarodermatitis						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vulvovaginitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis pneumococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cat scratch disease						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dacryocystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis shigella						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Genitourinary tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Groin abscess						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

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Helicobacter gastritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Impetigo North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infectious colitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Injection site abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lice infestation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oophoritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis chronic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Skin infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Staphylococcal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidiasis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tinea cruris						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tonsillitis bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tracheitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection bacterial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Viral tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	17/ 47 (36%)	3/ 62 (5%)	11.1444 (3.0260, 41.0435) /<.001	31.3315 (16.5928, 46.0702) /<.001	7.4752 (2.3261, 24.0218) /<.001	0.815
Europe	111/213 (52%)	17/192 (9%)	11.2024 (6.3616, 19.7268) /<.001	43.2585 (35.4384, 51.0786) /<.001	5.8857 (3.6722, 9.4334) /<.001	
Rest of World	8/ 23 (35%)	1/ 29 (3%)	14.9333 (1.7027, 130.9723) /0.015	31.3343 (10.7680, 51.9007) /0.003	10.0869 (1.3576, 74.9462) /0.024	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	16/ 47 (34%)	0/ 62	>999 (>999, >999) /NC	34.8196 (6.4113, 63.2280) /0.016	>999 (>999, >999) /NC	NC
Europe	101/213 (47%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	7/ 23 (30%)	0/ 29	>999 (>999, >999) /NC	31.3875 (-9.7264, 72.5013) /0.135	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	4/ 47 (9%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	34/213 (16%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	29/213 (14%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	17/213 (8%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.463
Europe	11/213 (5%)	2/192 (1%)	5.1733 (1.1319, 23.6439) /0.034	4.1227 (0.8219, 7.4235) /0.014	4.9577 (1.1129, 22.0852) /0.036	
Rest of World	3/ 23 (13%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
North America	4/ 47 (9%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	12/213 (6%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	7/192 (4%)	0.8981 (0.3092, 2.6085) /0.843	-0.3594 (-3.9317, 3.2128) /0.844	0.9014 (0.3220, 2.5232) /0.843	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	0.424
Europe	3/213 (1%)	6/192 (3%)	0.4429 (0.1092, 1.7957) /0.254	-1.7165 (-4.6425, 1.2094) /0.250	0.4507 (0.1143, 1.7774) /0.255	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	10/213 (5%)	1/192 (<1%)	9.4088 (1.1931, 74.1984) /0.033	4.1740 (1.1563, 7.1917) /0.007	9.0141 (1.1647, 69.7656) /0.035	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site erythema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	9/213 (4%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site warmth						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	6/213 (3%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Malaise North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site bruising						
North America	4/ 47 (9%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Discomfort North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site haematoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nodule North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Chest discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site granuloma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site necrosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site scar						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oedema peripheral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Swelling North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site bruise						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Gastrointestinal disorders						
Any Event						
North America	12/ 47 (26%)	10/ 62 (16%)	1.7829 (0.6948, 4.5745) /0.229	9.4029 (-6.0637, 24.8695) /0.233	1.5830 (0.7487, 3.3469) /0.229	0.026
Europe	56/213 (26%)	39/192 (20%)	1.3993 (0.8785, 2.2288) /0.157	5.9786 (-2.2272, 14.1844) /0.153	1.2943 (0.9037, 1.8538) /0.159	
Rest of World	4/ 23 (17%)	13/ 29 (45%)	0.2591 (0.0704, 0.9537) /0.042	-27.4363 (-51.2600, -3.6126) /0.024	0.3880 (0.1459, 1.0316) /0.058	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea North America	2/ 47 (4%)	3/ 62 (5%)	0.8741 (0.1401, 5.4530) /0.885	-0.5834 (-8.4466, 7.2798) /0.884	0.8794 (0.1530, 5.0536) /0.885	0.722
Europe	17/213 (8%)	15/192 (8%)	1.0235 (0.4965, 2.1099) /0.950	0.1687 (-5.0901, 5.4275) /0.950	1.0216 (0.5247, 1.9892) /0.950	
Rest of World	1/ 23 (4%)	3/ 29 (10%)	0.3939 (0.0382, 4.0623) /0.434	-5.9970 (-19.8648, 7.8708) /0.397	0.4203 (0.0468, 3.7780) /0.439	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Nausea						
North America	6/ 47 (13%)	3/ 62 (5%)	2.8780 (0.6805, 12.1724) /0.151	7.9272 (-3.0066, 18.8611) /0.155	2.6383 (0.6956, 10.0060) /0.154	0.010
Europe	9/213 (4%)	2/192 (1%)	4.1912 (0.8941, 19.6455) /0.069	3.1837 (0.1241, 6.2432) /0.041	4.0563 (0.8874, 18.5411) /0.071	
Rest of World	0/ 23	4/ 29 (14%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

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Abdominal pain						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.172
Europe	5/213 (2%)	5/192 (3%)	0.8990 (0.2562, 3.1544) /0.868	-0.2567 (-3.2914, 2.7779) /0.868	0.9014 (0.2650, 3.0659) /0.868	
Rest of World	1/ 23 (4%)	2/ 29 (7%)	0.6136 (0.0521, 7.2227) /0.698	-2.5487 (-14.9791, 9.8817) /0.688	0.6304 (0.0609, 6.5267) /0.699	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.520
Europe	10/213 (5%)	2/192 (1%)	4.6798 (1.0123, 21.6342) /0.048	3.6532 (0.4701, 6.8363) /0.024	4.5070 (1.0000, 20.3126) /0.050	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Dyspepsia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Toothache North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	6/213 (3%)	3/192 (2%)	1.8261 (0.4504, 7.4041) /0.399	1.2544 (-1.5766, 4.0854) /0.385	1.8028 (0.4571, 7.1097) /0.400	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	6/213 (3%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	2/192 (1%)	1.8182 (0.3293, 10.0397) /0.493	0.8363 (-1.4844, 3.1570) /0.480	1.8028 (0.3339, 9.7326) /0.493	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.146
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	2/ 29 (7%)	0.6136 (0.0521, 7.2227) /0.698	-2.5487 (-14.9791, 9.8817) /0.688	0.6304 (0.0609, 6.5267) /0.699	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.204
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.986
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Abdominal pain lower						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

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Anal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroduodentis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival bleeding						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stomatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aerophagia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal inflammation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aphthous ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bile acid malabsorption						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bowel movement irregularity						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis microscopic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysbacteriosiss						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal sounds abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival swelling						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukoplakia oral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Oesophageal polyp						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	
Palatal ulcer						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rectal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	7/ 47 (15%)	10/ 62 (16%)	0.9100 (0.3184, 2.6009) /0.860	-1.2354 (-14.9254, 12.4546) /0.860	0.9234 (0.3798, 2.2450) /0.860	0.269
Europe	35/213 (16%)	23/192 (12%)	1.4448 (0.8198, 2.5462) /0.203	4.4528 (-2.3194, 11.2249) /0.198	1.3717 (0.8415, 2.2359) /0.205	
Rest of World	4/ 23 (17%)	1/ 29 (3%)	5.8947 (0.6106, 56.9106) /0.125	13.9430 (-2.9109, 30.7970) /0.105	5.0435 (0.6042, 42.0964) /0.135	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	3/ 47 (6%)	1/ 62 (2%)	4.1591 (0.4186, 41.3233) /0.224	4.7701 (-2.8897, 12.4299) /0.222	3.9574 (0.4250, 36.8479) /0.227	0.666
Europe	11/213 (5%)	7/192 (4%)	1.4392 (0.5464, 3.7904) /0.461	1.5185 (-2.4641, 5.5011) /0.455	1.4165 (0.5604, 3.5806) /0.462	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.148
Europe	10/213 (5%)	3/192 (2%)	3.1034 (0.8413, 11.4483) /0.089	3.1323 (-0.2064, 6.4710) /0.066	3.0047 (0.8393, 10.7570) /0.091	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.925
Europe	5/213 (2%)	4/192 (2%)	1.1298 (0.2990, 4.2697) /0.857	0.2641 (-2.6022, 3.1304) /0.857	1.1268 (0.3070, 4.1354) /0.857	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Muscle contracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Musculoskeletal pain						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Muscle spasms						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal chest pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pain in extremity						
North America	3/ 47 (6%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Neck pain North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tendonitis						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.982
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Musculoskeletal discomfort						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteochondros is						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal stiffness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteonecrosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Soft tissue mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Spinal osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Tendon pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Nervous system disorders						
Any Event						
North America	7/ 47 (15%)	4/ 62 (6%)	2.5375 (0.6965, 9.2443) /0.158	8.4420 (-3.4321, 20.3161) /0.163	2.3085 (0.7175, 7.4270) /0.161	0.819
Europe	37/213 (17%)	17/192 (9%)	2.1641 (1.1744, 3.9877) /0.013	8.5167 (2.0334, 15.0000) /0.010	1.9619 (1.1431, 3.3671) /0.014	
Rest of World	3/ 23 (13%)	3/ 29 (10%)	1.3000 (0.2367, 7.1387) /0.763	2.6987 (-14.9732, 20.3705) /0.765	1.2609 (0.2803, 5.6725) /0.763	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Headache						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.372
Europe	25/213 (12%)	12/192 (6%)	1.9947 (0.9728, 4.0898) /0.059	5.4871 (-0.0271, 11.0013) /0.051	1.8779 (0.9705, 3.6338) /0.061	
Rest of World	1/ 23 (4%)	3/ 29 (10%)	0.3939 (0.0382, 4.0623) /0.434	-5.9970 (-19.8648, 7.8708) /0.397	0.4203 (0.0468, 3.7780) /0.439	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dizziness						
North America	4/ 47 (9%)	1/ 62 (2%)	5.6744 (0.6127, 52.5494) /0.126	6.8977 (-1.6739, 15.4693) /0.115	5.2766 (0.6096, 45.6750) /0.131	0.981
Europe	9/213 (4%)	2/192 (1%)	4.1912 (0.8941, 19.6455) /0.069	3.1837 (0.1241, 6.2432) /0.041	4.0563 (0.8874, 18.5411) /0.071	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Paraesthesia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Sciatica North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lethargy North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Migraine North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Presyncope						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoaesthesia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tremor						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Visual field defect						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Skin and subcutaneous tissue disorders						
Any Event						
North America	6/ 47 (13%)	6/ 62 (10%)	1.3659 (0.4109, 4.5400) /0.611	3.0885 (-8.9604, 15.1375) /0.615	1.3191 (0.4542, 3.8313) /0.611	0.407
Europe	30/213 (14%)	14/192 (7%)	2.0843 (1.0697, 4.0614) /0.031	6.7928 (0.8473, 12.7383) /0.025	1.9316 (1.0562, 3.5325) /0.033	
Rest of World	3/ 23 (13%)	5/ 29 (17%)	0.7200 (0.1529, 3.3905) /0.678	-4.1979 (-23.6516, 15.2558) /0.672	0.7565 (0.2016, 2.8394) /0.679	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eczema North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	2/192 (1%)	3.2282 (0.6624, 15.7320) /0.147	2.2447 (-0.5472, 5.0366) /0.115	3.1549 (0.6634, 15.0035) /0.149	
Rest of World	0/ 23	3/ 29 (10%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Rash						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.408
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Acne						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Seborrhoeic dermatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Dermatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Skin lesion						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papule North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis allergic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyshidrotic eczema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Ephelides North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Granuloma annulare						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lipodystrophy acquired						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Night sweats						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Penile ulceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pityriasis alba						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Psoriasis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin erosion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin hyperpigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypopigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin induration						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin reaction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xeroderma North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	5/ 47 (11%)	7/ 62 (11%)	0.9354 (0.2773, 3.1553) /0.914	-0.6520 (-12.4739, 11.1698) /0.914	0.9422 (0.3190, 2.7836) /0.914	0.359
Europe	23/213 (11%)	16/192 (8%)	1.3316 (0.6813, 2.6027) /0.402	2.4648 (-3.2497, 8.1793) /0.398	1.2958 (0.7058, 2.3789) /0.403	
Rest of World	1/ 23 (4%)	4/ 29 (14%)	0.2841 (0.0295, 2.7360) /0.276	-9.4453 (-24.5107, 5.6202) /0.219	0.3152 (0.0378, 2.6310) /0.286	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough North America	2/ 47 (4%)	3/ 62 (5%)	0.8741 (0.1401, 5.4530) /0.885	-0.5834 (-8.4466, 7.2798) /0.884	0.8794 (0.1530, 5.0536) /0.885	0.408
Europe	3/213 (1%)	4/192 (2%)	0.6714 (0.1484, 3.0389) /0.605	-0.6749 (-3.2412, 1.8914) /0.606	0.6761 (0.1533, 2.9823) /0.605	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.531
Europe	7/213 (3%)	2/192 (1%)	3.2282 (0.6624, 15.7320) /0.147	2.2447 (-0.5472, 5.0366) /0.115	3.1549 (0.6634, 15.0035) /0.149	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.233
Europe	5/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	3/192 (2%)	0.9000 (0.1795, 4.5130) /0.898	-0.1540 (-2.5166, 2.2085) /0.898	0.9014 (0.1841, 4.4131) /0.898	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	3/192 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchial obstruction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis chronic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal obstruction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reflux laryngitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillar hypertrophy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Wheezing North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	4/ 47 (9%)	4/ 62 (6%)	1.3488 (0.3193, 5.6984) /0.684	2.0590 (-7.9926, 12.1106) /0.688	1.3191 (0.3478, 5.0030) /0.684	0.527
Europe	21/213 (10%)	13/192 (7%)	1.5060 (0.7323, 3.0972) /0.266	3.0883 (-2.2650, 8.4416) /0.258	1.4561 (0.7499, 2.8275) /0.267	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	9/213 (4%)	2/192 (1%)	4.1912 (0.8941, 19.6455) /0.069	3.1837 (0.1241, 6.2432) /0.041	4.0563 (0.8874, 18.5411) /0.071	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.236
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Depression North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Sleep disorder						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affect lability						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paranoia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	2/ 47 (4%)	4/ 62 (6%)	0.6444 (0.1129, 3.6770) /0.621	-2.1963 (-10.6043, 6.2117) /0.609	0.6596 (0.1261, 3.4499) /0.622	0.355
Europe	16/213 (8%)	17/192 (9%)	0.8361 (0.4101, 1.7046) /0.622	-1.3424 (-6.6975, 4.0126) /0.623	0.8484 (0.4410, 1.6320) /0.622	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Arthropod bite						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	0.550
Europe	1/213 (<1%)	3/192 (2%)	0.2972 (0.0307, 2.8812) /0.295	-1.0930 (-3.0729, 0.8869) /0.279	0.3005 (0.0315, 2.8644) /0.296	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Laceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Thermal burn						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Arthropod sting						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Penis injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Craniocerebral injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epicondylitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injury North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Limb injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

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Multiple injuries						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Neck injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Penile contusion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Post procedural haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Skin injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Soft tissue injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Traumatic haematoma						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urethral injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Wound						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Metabolism and nutrition disorders						
Any Event						
North America	5/ 47 (11%)	4/ 62 (6%)	1.7262 (0.4371, 6.8166) /0.436	4.1867 (-6.5415, 14.9149) /0.444	1.6489 (0.4682, 5.8071) /0.436	0.998
Europe	21/213 (10%)	11/192 (6%)	1.7997 (0.8440, 3.8376) /0.128	4.1300 (-1.0502, 9.3101) /0.118	1.7209 (0.8521, 3.4756) /0.130	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	5/ 47 (11%)	2/ 62 (3%)	3.5714 (0.6613, 19.2890) /0.139	7.4125 (-2.4385, 17.2635) /0.140	3.2979 (0.6689, 16.2596) /0.143	0.796
Europe	16/213 (8%)	8/192 (4%)	1.8680 (0.7809, 4.4684) /0.160	3.3451 (-1.1847, 7.8749) /0.148	1.8028 (0.7893, 4.1178) /0.162	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypovitaminosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glucose tolerance impaired						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypocalcaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypomagnesaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Type 2 diabetes mellitus						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	0.284
Europe	16/213 (8%)	12/192 (6%)	1.2183 (0.5611, 2.6451) /0.618	1.2617 (-3.6630, 6.1865) /0.616	1.2019 (0.5835, 2.4756) /0.618	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Anogenital warts						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	11/213 (5%)	3/192 (2%)	3.4307 (0.9426, 12.4869) /0.061	3.6018 (0.1507, 7.0529) /0.041	3.3052 (0.9360, 11.6709) /0.063	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Skin papilloma						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Acrochordon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Melanocytic naevus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Oral papilloma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign spleen tumour						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysplastic naevus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neoplasm skin						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral fibroma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.144
Europe	19/213 (9%)	8/192 (4%)	2.2526 (0.9625, 5.2719) /0.061	4.7535 (-0.0048, 9.5118) /0.050	2.1408 (0.9594, 4.7774) /0.063	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	9/213 (4%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carbon dioxide decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heart rate increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nuclear magnetic resonance imaging brain abnormal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Protein urine present						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Total lung capacity decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.293
Europe	12/213 (6%)	10/192 (5%)	1.0866 (0.4585, 2.5750) /0.850	0.4255 (-3.9866, 4.8375) /0.850	1.0817 (0.4782, 2.4467) /0.850	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrophic vulvovaginitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital lesion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Breast discharge						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Breast pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Cervix disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Dysfunctional uterine bleeding						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dysmenorrhoea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Menopausal symptoms						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Penile pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Polymenorrhoe ^a						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vaginal discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vaginal dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vaginal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vaginal ulceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvar dysplasia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	NC
Europe	10/213 (5%)	5/192 (3%)	1.8424 (0.6184, 5.4893) /0.273	2.0907 (-1.5348, 5.7162) /0.258	1.8028 (0.6273, 5.1810) /0.274	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	0.905
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Normocytic anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splenomegaly						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.250
Europe	9/213 (4%)	7/192 (4%)	1.1660 (0.4257, 3.1935) /0.765	0.5795 (-3.2056, 4.3646) /0.764	1.1590 (0.4401, 3.0520) /0.765	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	5/213 (2%)	2/192 (1%)	2.2837 (0.4379, 11.9097) /0.327	1.3058 (-1.1835, 3.7950) /0.304	2.2535 (0.4423, 11.4808) /0.328	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Calculus urinary						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nephrolithiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Nephropathy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pollakiuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral caruncle						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary incontinence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Eye disorders						
Any Event						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.155
Europe	7/213 (3%)	3/192 (2%)	2.1408 (0.5457, 8.3981) /0.275	1.7239 (-1.2442, 4.6920) /0.255	2.1033 (0.5516, 8.0194) /0.276	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenopia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharospasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye irritation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glare						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meibomian gland dysfunction						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myopia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Uveitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/ 47	3/ 62 (5%)	<0.0001 (<0.0001, -) />0.999	-7.0163 (-36.5801, 22.5475) /0.642	<0.0001 (<0.0001, -) />0.999	NC
Europe	7/213 (3%)	3/192 (2%)	2.1408 (0.5457, 8.3981) /0.275	1.7239 (-1.2442, 4.6920) /0.255	2.1033 (0.5516, 8.0194) /0.276	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Noninfective myringitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinnitus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Immune system disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.563
Europe	8/213 (4%)	2/192 (1%)	3.7073 (0.7775, 17.6779) /0.100	2.7142 (-0.2153, 5.6437) /0.069	3.6056 (0.7752, 16.7712) /0.102	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.264
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypersensitivity						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mite allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vascular disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hot flush						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Hyperaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Intermittent claudication						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Peripheral venous disease						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 1

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Atrioventricular block first degree						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Cardiovascular disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gilbert's syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Keratosis follicular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis toxic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth extraction						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	27/ 47 (57%)	24/ 62 (39%)	2.1375 (0.9880, 4.6243) /0.054	18.7371 (0.1146, 37.3597) /0.049	1.4840 (0.9965, 2.2102) /0.052	0.878
Europe	102/213 (48%)	61/192 (32%)	1.9734 (1.3153, 2.9607) /0.001	16.1165 (6.7156, 25.5174) /<.001	1.5073 (1.1736, 1.9357) /0.001	
Rest of World	14/ 23 (61%)	10/ 29 (34%)	2.9556 (0.9503, 9.1925) /0.061	26.3868 (-0.0155, 52.7891) /0.050	1.7652 (0.9695, 3.2139) /0.063	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	11/ 47 (23%)	14/ 62 (23%)	1.0476 (0.4258, 2.5772) /0.919	0.8236 (-15.1400, 16.7872) /0.919	1.0365 (0.5184, 2.0722) /0.919	0.636
Europe	40/213 (19%)	31/192 (16%)	1.2008 (0.7169, 2.0113) /0.487	2.6335 (-4.7554, 10.0225) /0.485	1.1631 (0.7593, 1.7818) /0.487	
Rest of World	5/ 23 (22%)	3/ 29 (10%)	2.4074 (0.5097, 11.3697) /0.267	11.3943 (-8.7802, 31.5688) /0.268	2.1014 (0.5599, 7.8872) /0.271	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.239
Europe	5/213 (2%)	3/192 (2%)	1.5144 (0.3571, 6.4229) /0.573	0.7849 (-1.9005, 3.4703) /0.567	1.5023 (0.3639, 6.2030) /0.574	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	4/ 47 (9%)	2/ 62 (3%)	2.7907 (0.4889, 15.9309) /0.248	5.2848 (-3.8246, 14.3943) /0.256	2.6383 (0.5044, 13.7996) /0.250	0.475
Europe	2/213 (<1%)	3/192 (2%)	0.5972 (0.0987, 3.6123) /0.575	-0.6235 (-2.8041, 1.5570) /0.575	0.6009 (0.1015, 3.5583) /0.575	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	0.785
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urinary tract infection						
North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Ear infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.248
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

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Proctitis chlamydial						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vulvovaginal candidiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Acarodermatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Onychomycosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Orchitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Otitis media						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Skin infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tracheitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Acute hepatitis C						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Escherichia urinary tract infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Pneumonia North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid infection						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital candidiasis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary chlamydia infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract gonococcal infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranulo ma venereum						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaria North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pharyngitis streptococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Post procedural infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Proctitis mycoplasmal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urethritis mycoplasmal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vulvovaginal mycotic infection						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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General disorders and administration site conditions						
Any Event						
North America	21/ 47 (45%)	2/ 62 (3%)	24.2308 (5.2908, 110.9719) /<.001	41.4550 (26.5768, 56.3333) /<.001	13.8510 (3.4157, 56.1678) /<.001	NC
Europe	69/213 (32%)	2/192 (1%)	45.5208 (10.9764, 188.7827) /<.001	31.3527 (24.9060, 37.7994) /<.001	31.0986 (7.7285, 125.1374) /<.001	
Rest of World	6/ 23 (26%)	0/ 29	>999 (>999, >999) /NC	27.2511 (-13.5513, 68.0536) /0.191	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	20/ 47 (43%)	0/ 62	>999 (>999, >999) /NC	42.9157 (14.2759, 71.5555) /0.003	NC	NC
Europe	67/213 (31%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	5/ 23 (22%)	0/ 29	>999 (>999, >999) /NC	23.1145 (-17.3126, 63.5415) /0.262	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site induration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	8/213 (4%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site swelling						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.413
Europe	4/213 (2%)	2/192 (1%)	1.8182 (0.3293, 10.0397) /0.493	0.8363 (-1.4844, 3.1570) /0.480	1.8028 (0.3339, 9.7326) /0.493	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Injection site warmth						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site bruising						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Discomfort North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Injection site haematoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Chest pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site discolouration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Feeling hot						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Catheter site erythema						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Injection site discomfort						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Gastrointestinal disorders						
Any Event						
North America	4/ 47 (9%)	3/ 62 (5%)	1.8295 (0.3892, 8.5994) /0.444	3.6719 (-5.9286, 13.2724) /0.453	1.7589 (0.4133, 7.4844) /0.445	0.648
Europe	29/213 (14%)	8/192 (4%)	3.6250 (1.6143, 8.1401) /0.002	9.4484 (4.0446, 14.8521) /<.001	3.2676 (1.5312, 6.9733) /0.002	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Diarrhoea						
North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	0.996
Europe	10/213 (5%)	3/192 (2%)	3.1034 (0.8413, 11.4483) /0.089	3.1323 (-0.2064, 6.4710) /0.066	3.0047 (0.8393, 10.7570) /0.091	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dyspepsia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal inflammation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea haemorrhagic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Barrett's oesophagus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia oral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth development disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Umbilical hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.105
Europe	15/213 (7%)	6/192 (3%)	2.3485 (0.8923, 6.1808) /0.084	3.9173 (-0.3092, 8.1438) /0.069	2.2535 (0.8923, 5.6913) /0.086	
Rest of World	0/ 23	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	7/213 (3%)	4/192 (2%)	1.5971 (0.4602, 5.5426) /0.461	1.2031 (-1.9296, 4.3357) /0.452	1.5775 (0.4690, 5.3053) /0.461	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Myalgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Pain in extremity						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Neck pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteochondros is						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Musculoskeletal stiffness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Spinal osteoarthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Osteoporosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rotator cuff syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Temporomandibular joint syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nervous system disorders						
Any Event						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.034
Europe	11/213 (5%)	9/192 (5%)	1.1073 (0.4487, 2.7326) /0.825	0.4768 (-3.7388, 4.6925) /0.825	1.1017 (0.4666, 2.6011) /0.825	
Rest of World	3/ 23 (13%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Headache North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	0.144
Europe	7/213 (3%)	4/192 (2%)	1.5971 (0.4602, 5.5426) /0.461	1.2031 (-1.9296, 4.3357) /0.452	1.5775 (0.4690, 5.3053) /0.461	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dizziness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anosmia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical neuritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nerve compression						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigeminal neuralgia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.372
Europe	4/213 (2%)	5/192 (3%)	0.7158 (0.1894, 2.7051) /0.622	-0.7262 (-3.6241, 2.1717) /0.623	0.7211 (0.1965, 2.6467) /0.622	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Eczema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rash						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Hyperhidrosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dermatitis atopic						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Dyshidrotic eczema						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rash vesicular						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Urticaria						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail pigmentation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Rash morbilliform						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.568
Europe	11/213 (5%)	4/192 (2%)	2.5594 (0.8012, 8.1764) /0.113	3.0810 (-0.5127, 6.6746) /0.093	2.4789 (0.8027, 7.6556) /0.115	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough North America	0/ 47	2/ 62 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-34.9549, 24.0201) /0.716	<0.0001 (<0.0001, -) />0.999	NC
Europe	5/213 (2%)	1/192 (<1%)	4.5913 (0.5316, 39.6528) /0.166	1.8266 (-0.4474, 4.1005) /0.115	4.5070 (0.5313, 38.2367) /0.168	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Asthma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Respiratory disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Nasal turbinate hypertrophy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Psychiatric disorders						
Any Event						
North America	3/ 47 (6%)	3/ 62 (5%)	1.3409 (0.2582, 6.9628) /0.727	1.5443 (-7.2517, 10.3403) /0.731	1.3191 (0.2787, 6.2448) /0.727	0.999
Europe	7/213 (3%)	5/192 (3%)	1.2709 (0.3966, 4.0726) /0.687	0.6822 (-2.6052, 3.9696) /0.684	1.2620 (0.4073, 3.9103) /0.687	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Anxiety North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	2/192 (1%)	1.3571 (0.2244, 8.2096) /0.739	0.3668 (-1.7702, 2.5038) /0.737	1.3521 (0.2284, 8.0061) /0.740	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Insomnia North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Depression North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.248
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Libido decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Adjustment disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Panic attack						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Adjustment disorder with depressed mood						
North America	2/ 47 (4%)	0/ 62	>999 (>999, >999) /NC	6.4573 (-19.8471, 32.7618) /0.630	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affective disorder						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
North America	3/ 47 (6%)	2/ 62 (3%)	2.0455 (0.3278, 12.7638) /0.444	3.1572 (-5.1001, 11.4144) /0.454	1.9787 (0.3443, 11.3705) /0.444	0.597
Europe	8/213 (4%)	10/192 (5%)	0.7102 (0.2744, 1.8381) /0.481	-1.4525 (-5.5018, 2.5969) /0.482	0.7211 (0.2906, 1.7897) /0.481	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wound						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ankle fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Exposure via inhalation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fracture North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Joint dislocation						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Joint injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Rib fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Tibia fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
North America	1/ 47 (2%)	2/ 62 (3%)	0.6522 (0.0574, 7.4153) /0.730	-1.0981 (-7.1282, 4.9320) /0.721	0.6596 (0.0616, 7.0581) /0.731	0.473
Europe	2/213 (<1%)	4/192 (2%)	0.4455 (0.0807, 2.4600) /0.354	-1.1444 (-3.5441, 1.2554) /0.350	0.4507 (0.0835, 2.4332) /0.354	
Rest of World	2/ 23 (9%)	1/ 29 (3%)	2.6667 (0.2264, 31.4080) /0.436	5.2474 (-8.0458, 18.5405) /0.439	2.5217 (0.2436, 26.1066) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.588
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital warts						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Anal neoplasm						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

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Breast cancer						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Kaposi's sarcoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Kidney angiomyolipom a						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Investigations						
Any Event						
North America	1/ 47 (2%)	3/ 62 (5%)	0.4275 (0.0430, 4.2463) /0.468	-2.7111 (-9.4601, 4.0380) /0.431	0.4397 (0.0472, 4.0942) /0.470	0.289
Europe	7/213 (3%)	8/192 (4%)	0.7816 (0.2780, 2.1972) /0.640	-0.8803 (-4.5845, 2.8240) /0.641	0.7887 (0.2915, 2.1343) /0.640	
Rest of World	3/ 23 (13%)	1/ 29 (3%)	4.2000 (0.4067, 43.3743) /0.228	9.5952 (-5.6868, 24.8772) /0.218	3.7826 (0.4208, 34.0020) /0.235	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Blood creatine phosphokinase increased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/213 (1%)	1/192 (<1%)	2.7286 (0.2814, 26.4540) /0.386	0.8876 (-0.9941, 2.7694) /0.355	2.7042 (0.2837, 25.7791) /0.387	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Creatinine renal clearance decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Aspartate aminotransferase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Glomerular filtration rate decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood folate decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma test positive						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Platelet count decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Treponema test positive						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.997
Europe	4/213 (2%)	3/192 (2%)	1.2057 (0.2664, 5.4571) /0.808	0.3154 (-2.2145, 2.8454) /0.807	1.2019 (0.2724, 5.3019) /0.808	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

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Prostatitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstruation irregular						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	4/192 (2%)	0.2217 (0.0246, 2.0010) /0.180	-1.6138 (-3.8329, 0.6052) /0.154	0.2254 (0.0254, 1.9987) /0.181	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypochromic anaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	1/192 (<1%)	3.6555 (0.4050, 32.9930) /0.248	1.3571 (-0.7309, 3.4451) /0.203	3.6056 (0.4065, 31.9798) /0.249	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chorioretinal disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic retinopathy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye allergy						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glaucoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vertigo North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Vascular disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hypertension						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Circulatory collapse						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hypertensive crisis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Peripheral ischaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis superficial						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Goitre						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbilirubi naemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic steatosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocholecystis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	2/ 47 (4%)	2/ 62 (3%)	1.3333 (0.1809, 9.8295) /0.778	1.0295 (-6.2260, 8.2850) /0.781	1.3191 (0.1928, 9.0245) /0.778	0.277
Europe	21/213 (10%)	7/192 (4%)	2.8906 (1.2003, 6.9614) /0.018	6.2133 (1.4116, 11.0150) /0.011	2.7042 (1.1758, 6.2194) /0.019	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	2/192 (1%)	0.4481 (0.0403, 4.9814) /0.514	-0.5722 (-2.2766, 1.1323) /0.511	0.4507 (0.0412, 4.9312) /0.514	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	10/213 (5%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	10/213 (5%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin cancer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	0.194
Europe	5/213 (2%)	2/192 (1%)	2.2837 (0.4379, 11.9097) /0.327	1.3058 (-1.1835, 3.7950) /0.304	2.2535 (0.4423, 11.4808) /0.328	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bile duct stone						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cholecystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic cirrhosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	2/ 47 (4%)	1/ 62 (2%)	2.7111 (0.2384, 30.8308) /0.421	2.6424 (-3.9251, 9.2099) /0.430	2.6383 (0.2465, 28.2324) /0.422	NC
Europe	5/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
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 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 4

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Laceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Road traffic accident						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Metabolism and nutrition disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Diabetic ketoacidosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Investigations						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/213 (1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Blood creatine phosphokinase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Lipase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Region - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	72/227 (32%)	98/227 (43%)	0.6115 (0.4167, 0.8973) /0.012	-11.4537 (-20.2950, -2.6124) /0.011	0.7347 (0.5766, 0.9361) /0.013	0.261
>=100,000	21/ 56 (38%)	21/ 56 (38%)	1.0000 (0.4653, 2.1492) />0.999	<0.0001 (-17.9318, 17.9318) />0.999	1.0000 (0.6199, 1.6131) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<100,000	103/227 (45%)	99/227 (44%)	1.0740 (0.7416, 1.5552) /0.706	1.7621 (-7.3791, 10.9033) /0.706	1.0404 (0.8471, 1.2778) /0.706	0.508
>=100,000	29/ 56 (52%)	24/ 56 (43%)	1.4321 (0.6799, 3.0163) /0.345	8.9286 (-9.4907, 27.3478) /0.342	1.2083 (0.8147, 1.7921) /0.347	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<100,000	43/227 (19%)	34/227 (15%)	1.3266 (0.8102, 2.1720) /0.261	3.9648 (-2.9298, 10.8593) /0.260	1.2647 (0.8389, 1.9065) /0.262	0.233
>=100,000	7/ 56 (13%)	10/ 56 (18%)	0.6571 (0.2308, 1.8710) /0.432	-5.3571 (-18.6104, 7.8962) /0.428	0.7000 (0.2869, 1.7081) /0.433	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<100,000	28/227 (12%)	15/227 (7%)	1.9886 (1.0316, 3.8333) /0.040	5.7269 (0.3657, 11.0881) /0.036	1.8667 (1.0249, 3.3997) /0.041	0.038
>=100,000	4/ 56 (7%)	8/ 56 (14%)	0.4615 (0.1306, 1.6315) /0.230	-7.1429 (-18.5225, 4.2367) /0.219	0.5000 (0.1596, 1.5660) /0.234	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <100,000	15/227 (7%)	13/227 (6%)	1.1647 (0.5411, 2.5070) /0.697	0.8811 (-3.5439, 5.3060) /0.696	1.1538 (0.5619, 2.3694) /0.697	0.600
>=100,000	3/ 56 (5%)	4/ 56 (7%)	0.7358 (0.1570, 3.4498) /0.697	-1.7857 (-10.7455, 7.1741) /0.696	0.7500 (0.1759, 3.1986) /0.697	
Gastroenteritis <100,000	10/227 (4%)	7/227 (3%)	1.4483 (0.5414, 3.8741) /0.461	1.3216 (-2.1690, 4.8122) /0.458	1.4286 (0.5535, 3.6872) /0.461	0.962
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis <100,000	10/227 (4%)	9/227 (4%)	1.1162 (0.4449, 2.8008) /0.815	0.4405 (-3.2432, 4.1243) /0.815	1.1111 (0.4602, 2.6829) /0.815	0.060
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<100,000	11/227 (5%)	6/227 (3%)	1.8758 (0.6817, 5.1617) /0.223	2.2026 (-1.2842, 5.6894) /0.216	1.8333 (0.6898, 4.8729) /0.224	0.157
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis <100,000	6/227 (3%)	6/227 (3%)	1.0000 (0.3176, 3.1482) />0.999	<0.0001 (-2.9512, 2.9512) />0.999	1.0000 (0.3274, 3.0542) />0.999	>0.999
>=100,000	3/ 56 (5%)	3/ 56 (5%)	1.0000 (0.1930, 5.1809) />0.999	<0.0001 (-8.3403, 8.3403) />0.999	1.0000 (0.2108, 4.7438) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <100,000	5/227 (2%)	5/227 (2%)	1.0000 (0.2855, 3.5025) />0.999	<0.0001 (-2.7001, 2.7001) />0.999	1.0000 (0.2935, 3.4071) />0.999	0.376
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	
Bronchitis <100,000	7/227 (3%)	3/227 (1%)	2.3758 (0.6066, 9.3050) /0.214	1.7621 (-0.9332, 4.4574) /0.200	2.3333 (0.6110, 8.9105) /0.215	0.251
>=100,000	1/ 56 (2%)	2/ 56 (4%)	0.4909 (0.0432, 5.5742) /0.566	-1.7857 (-7.7569, 4.1855) /0.558	0.5000 (0.0467, 5.3578) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis <100,000	5/227 (2%)	3/227 (1%)	1.6817 (0.3971, 7.1216) /0.480	0.8811 (-1.5381, 3.3002) /0.475	1.6667 (0.4031, 6.8916) /0.481	0.927
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<100,000	2/227 (<1%)	7/227 (3%)	0.2794 (0.0574, 1.3596) /0.114	-2.2026 (-4.7591, 0.3538) /0.091	0.2857 (0.0600, 1.3606) /0.116	0.026
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis <100,000	4/227 (2%)	4/227 (2%)	1.0000 (0.2470, 4.0482) />0.999	<0.0001 (-2.4205, 2.4205) />0.999	1.0000 (0.2532, 3.9497) />0.999	0.614
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
Gonorrhoea <100,000	5/227 (2%)	5/227 (2%)	1.0000 (0.2855, 3.5025) />0.999	<0.0001 (-2.7001, 2.7001) />0.999	1.0000 (0.2935, 3.4071) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.774
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
Herpes simplex <100,000	4/227 (2%)	5/227 (2%)	0.7964 (0.2111, 3.0048) /0.737	-0.4405 (-3.0047, 2.1236) /0.736	0.8000 (0.2176, 2.9409) /0.737	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
<100,000	5/227 (2%)	2/227 (<1%)	2.5338 (0.4865, 13.1970) /0.270	1.3216 (-0.9419, 3.5850) /0.252	2.5000 (0.4901, 12.7529) /0.270	0.136
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <100,000	2/227 (<1%)	4/227 (2%)	0.4956 (0.0899, 2.7329) /0.420	-0.8811 (-2.9804, 1.2183) /0.411	0.5000 (0.0925, 2.7026) /0.421	0.242
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	0.130
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papilloma viral infection						
<100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.310
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth infection						
<100,000	6/227 (3%)	2/227 (<1%)	3.0543 (0.6099, 15.2959) /0.174	1.7621 (-0.6530, 4.1772) /0.153	3.0000 (0.6120, 14.7067) /0.176	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<100,000	1/227 (<1%)	6/227 (3%)	0.1630 (0.0195, 1.3648) /0.094	-2.2026 (-4.4603, 0.0550) /0.056	0.1667 (0.0202, 1.3733) /0.096	0.592
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum <100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.436
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.049
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Herpes zoster						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.406
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.049
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.206
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.086
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.134
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Lower respiratory tract infection <100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.134
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Body tinea <100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Fungal skin infection <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oropharyngeal gonococcal infection <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Tinea versicolour						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.187
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cystitis						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Proctitis gonococcal						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth abscess <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal infection <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanitis candida						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Candida infection						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Epididymitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Otitis externa						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Proctitis chlamydial <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tinea infection <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvovaginal candidiasis <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acarodermatitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal abscess						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anorectal human papilloma virus infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bacterial vulvovaginitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Cat scratch disease <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis bacterial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dacryocystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gastroenteritis shigella						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Genital infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gingivitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Helicobacter gastritis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes virus infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Impetigo						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infectious colitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site abscess						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lice infestation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Onychomycosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oophoritis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oral infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Otitis media <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pertussis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyelonephritis chronic						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection bacterial <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rotavirus infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin candida						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Staphylococcal abscess						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Strongyloidiasis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tinea cruris						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis bacterial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tracheitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection bacterial						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vaginal infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral tonsillitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vulvovaginitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<100,000	108/227 (48%)	16/227 (7%)	11.9685 (6.7611, 21.1866) /<.001	40.5286 (33.2283, 47.8290) /<.001	6.7500 (4.1280, 11.0374) /<.001	0.720
>=100,000	28/ 56 (50%)	5/ 56 (9%)	10.2000 (3.5432, 29.3631) /<.001	41.0714 (25.9959, 56.1470) /<.001	5.6000 (2.3309, 13.4542) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
<100,000	97/227 (43%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	27/ 56 (48%)	0/ 56	>999 (>999, >999) /NC	48.3009 (19.0215, 77.5804) /0.001	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<100,000	33/227 (15%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	6/ 56 (11%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration <100,000	26/227 (11%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
<100,000	16/227 (7%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
<100,000	12/227 (5%)	1/227 (<1%)	12.6140 (1.6263, 97.8393) /0.015	4.8458 (1.8102, 7.8815) /0.002	12.0000 (1.5734, 91.5227) /0.017	0.378
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
<100,000	15/227 (7%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<100,000	6/227 (3%)	5/227 (2%)	1.2054 (0.3626, 4.0075) /0.761	0.4405 (-2.3879, 3.2690) /0.760	1.2000 (0.3715, 3.8760) /0.761	0.506
>=100,000	1/ 56 (2%)	2/ 56 (4%)	0.4909 (0.0432, 5.5742) /0.566	-1.7857 (-7.7569, 4.1855) /0.558	0.5000 (0.0467, 5.3578) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <100,000	4/227 (2%)	6/227 (3%)	0.6607 (0.1839, 2.3733) /0.525	-0.8811 (-3.5800, 1.8179) /0.522	0.6667 (0.1907, 2.3309) /0.525	0.793
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia <100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Injection site erythema <100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Malaise						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nodule						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site haemorrhage						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chest pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site anaesthesia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cyst						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site discolouration						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site granuloma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site necrosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site scar						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Non-cardiac chest pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Swelling <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vessel puncture site bruise						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	57/227 (25%)	48/227 (21%)	1.2504 (0.8072, 1.9368) /0.317	3.9648 (-3.7838, 11.7133) /0.316	1.1875 (0.8478, 1.6634) /0.318	0.777
>=100,000	15/ 56 (27%)	14/ 56 (25%)	1.0976 (0.4710, 2.5575) /0.829	1.7857 (-14.4361, 18.0075) /0.829	1.0714 (0.5723, 2.0060) /0.829	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <100,000	15/227 (7%)	15/227 (7%)	1.0000 (0.4768, 2.0971) />0.999	<0.0001 (-4.5702, 4.5702) />0.999	1.0000 (0.5008, 1.9970) />0.999	0.787
>=100,000	5/ 56 (9%)	6/ 56 (11%)	0.8170 (0.2342, 2.8495) /0.751	-1.7857 (-12.8040, 9.2325) /0.751	0.8333 (0.2699, 2.5734) /0.751	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <100,000	13/227 (6%)	6/227 (3%)	2.2375 (0.8352, 5.9943) /0.109	3.0837 (-0.5893, 6.7567) /0.100	2.1667 (0.8382, 5.6006) /0.111	0.239
>=100,000	2/ 56 (4%)	3/ 56 (5%)	0.6543 (0.1051, 4.0744) /0.649	-1.7857 (-9.4280, 5.8565) /0.647	0.6667 (0.1158, 3.8381) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
<100,000	8/227 (4%)	3/227 (1%)	2.7275 (0.7143, 10.4157) /0.142	2.2026 (-0.6188, 5.0241) /0.126	2.6667 (0.7166, 9.9236) /0.143	0.005
>=100,000	0/ 56	4/ 56 (7%)	<0.0001 (<0.0001, -) />0.999	-9.2175 (-36.7480, 18.3129) /0.512	<0.0001 (<0.0001, -) />0.999	
Haemorrhoids						
<100,000	13/227 (6%)	2/227 (<1%)	6.8341 (1.5243, 30.6411) /0.012	4.8458 (1.5879, 8.1038) /0.004	6.5000 (1.4837, 28.4768) /0.013	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <100,000	5/227 (2%)	3/227 (1%)	1.6817 (0.3971, 7.1216) /0.480	0.8811 (-1.5381, 3.3002) /0.475	1.6667 (0.4031, 6.8916) /0.481	0.349
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Toothache <100,000	6/227 (3%)	3/227 (1%)	2.0271 (0.5007, 8.2066) /0.322	1.3216 (-1.2400, 3.8832) /0.312	2.0000 (0.5064, 7.8994) /0.323	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <100,000	6/227 (3%)	1/227 (<1%)	6.1357 (0.7327, 51.3795) /0.094	2.2026 (-0.0550, 4.4603) /0.056	6.0000 (0.7282, 49.4396) /0.096	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anogenital dysplasia <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.339
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.049
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	
Dental caries <100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	0.206
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.206
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.134
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.708
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.708
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.086
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.187
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Abdominal pain lower <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal fissure <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastroduodeni tis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival bleeding						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Haemorrhoidal haemorrhage						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Stomatitis <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Aerophagia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal inflammation <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal ulcer <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bile acid malabsorption						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bowel movement irregularity <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Colitis microscopic <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysbacterioses						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Enteritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Epigastric discomfort <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gastrointestinal sounds abnormal <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gingival swelling <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Inguinal hernia <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Leukoplakia oral						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphoid hyperplasia of intestine <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oesophageal polyp <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Palatal ulcer <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal discharge						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Rectal haemorrhage						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue eruption						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	37/227 (16%)	26/227 (11%)	1.5055 (0.8779, 2.5817) /0.137	4.8458 (-1.4985, 11.1901) /0.134	1.4231 (0.8924, 2.2692) /0.138	0.644
>=100,000	9/ 56 (16%)	8/ 56 (14%)	1.1489 (0.4086, 3.2305) /0.792	1.7857 (-11.5005, 15.0720) /0.792	1.1250 (0.4678, 2.7052) /0.792	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <100,000	12/227 (5%)	8/227 (4%)	1.5279 (0.6125, 3.8117) /0.363	1.7621 (-2.0097, 5.5340) /0.360	1.5000 (0.6250, 3.6000) /0.364	0.556
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	
Myalgia <100,000	9/227 (4%)	3/227 (1%)	3.0826 (0.8236, 11.5380) /0.095	2.6432 (-0.2980, 5.5843) /0.078	3.0000 (0.8228, 10.9380) /0.096	>0.999
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <100,000	3/227 (1%)	5/227 (2%)	0.5946 (0.1404, 2.5182) /0.480	-0.8811 (-3.3002, 1.5381) /0.475	0.6000 (0.1451, 2.4810) /0.481	0.206
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	
Muscle contracture <100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.339
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	
Muscle spasms						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.476
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pain in extremity						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.409
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Musculoskeletal discomfort <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondrosis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Plantar fasciitis						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal disorder						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bursitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin pain <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Intervertebral disc disorder <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Musculoskeletal stiffness						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Osteonecrosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue mass						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Spinal osteoarthritis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon pain <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<100,000	40/227 (18%)	18/227 (8%)	2.4837 (1.3764, 4.4815) /0.003	9.6916 (3.6154, 15.7678) /0.002	2.2222 (1.3146, 3.7565) /0.003	0.278
>=100,000	7/ 56 (13%)	6/ 56 (11%)	1.1905 (0.3734, 3.7953) /0.768	1.7857 (-10.0739, 13.6454) /0.768	1.1667 (0.4184, 3.2535) /0.768	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
<100,000	22/227 (10%)	11/227 (5%)	2.1073 (0.9968, 4.4548) /0.051	4.8458 (0.0904, 9.6013) /0.046	2.0000 (0.9932, 4.0275) /0.052	0.288
>=100,000	6/ 56 (11%)	6/ 56 (11%)	1.0000 (0.3019, 3.3120) />0.999	<0.0001 (-11.4562, 11.4562) />0.999	1.0000 (0.3433, 2.9132) />0.999	
Dizziness						
<100,000	11/227 (5%)	2/227 (<1%)	5.7292 (1.2553, 26.1469) /0.024	3.9648 (0.9183, 7.0112) /0.011	5.5000 (1.2329, 24.5352) /0.025	0.493
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia <100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Sciatica <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Migraine <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Somnolence <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Syncope						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
≥100,000	0/ 56	0/ 56	NC	NC	NC	
Amnesia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
≥100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Disturbance in attention						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoaesthesia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Intercostal neuralgia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Poor quality sleep						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tension headache						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tremor						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Visual field defect						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<100,000	30/227 (13%)	18/227 (8%)	1.7682 (0.9551, 3.2735) /0.070	5.2863 (-0.3496, 10.9223) /0.066	1.6667 (0.9571, 2.9022) /0.071	0.636
>=100,000	9/ 56 (16%)	7/ 56 (13%)	1.3404 (0.4618, 3.8911) /0.590	3.5714 (-9.3729, 16.5158) /0.589	1.2857 (0.5146, 3.2122) /0.591	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema						
<100,000	5/227 (2%)	3/227 (1%)	1.6817 (0.3971, 7.1216) /0.480	0.8811 (-1.5381, 3.3002) /0.475	1.6667 (0.4031, 6.8916) /0.481	0.675
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	
Rash						
<100,000	5/227 (2%)	3/227 (1%)	1.6817 (0.3971, 7.1216) /0.480	0.8811 (-1.5381, 3.3002) /0.475	1.6667 (0.4031, 6.8916) /0.481	0.068
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.134
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Seborrhoeic dermatitis						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin lesion <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Erythema <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Intertrigo <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papule						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pityriasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rash pruritic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin mass <100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
<hr/>						
Alopecia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood blister <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dermatitis allergic <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dyshidrotic eczema						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ephelides <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Granuloma annulare <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipodystrophy acquired						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Night sweats						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pityriasis alba						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Psoriasis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rash generalised <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash macular <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rash maculo-papular						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash papular						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash vesicular						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rosacea						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin erosion <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin hyperpigmentation <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypopigmentation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin induration						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin reaction <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Xeroderma <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<100,000	23/227 (10%)	21/227 (9%)	1.1060 (0.5935, 2.0609) /0.751	0.8811 (-4.5610, 6.3231) /0.751	1.0952 (0.6242, 1.9217) /0.751	0.883
>=100,000	6/ 56 (11%)	6/ 56 (11%)	1.0000 (0.3019, 3.3120) />0.999	<0.0001 (-11.4562, 11.4562) />0.999	1.0000 (0.3433, 2.9132) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
<100,000	5/227 (2%)	7/227 (3%)	0.7079 (0.2213, 2.2641) /0.560	-0.8811 (-3.8311, 2.0690) /0.558	0.7143 (0.2301, 2.2174) /0.560	0.160
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<100,000	7/227 (3%)	3/227 (1%)	2.3758 (0.6066, 9.3050) /0.214	1.7621 (-0.9332, 4.4574) /0.200	2.3333 (0.6110, 8.9105) /0.215	0.589
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	0.429
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Catarrh						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
<100,000	0/227	3/227 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.134
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea <100,000	0/227	4/227 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Asthma <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epistaxis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Productive cough <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bronchial obstruction						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis chronic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bronchospasm						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal dryness <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal obstruction <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal ulcer <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Reflux laryngitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tonsillar hypertrophy						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract inflammation <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Wheezing <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<100,000	23/227 (10%)	15/227 (7%)	1.5935 (0.8087, 3.1399) /0.178	3.5242 (-1.5603, 8.6088) /0.174	1.5333 (0.8216, 2.8615) /0.179	0.982
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety <100,000	7/227 (3%)	2/227 (<1%)	3.5795 (0.7355, 17.4206) /0.114	2.2026 (-0.3538, 4.7591) /0.091	3.5000 (0.7350, 16.6669) /0.116	0.703
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	
<hr/>						
Insomnia <100,000	5/227 (2%)	2/227 (<1%)	2.5338 (0.4865, 13.1970) /0.270	1.3216 (-0.9419, 3.5850) /0.252	2.5000 (0.4901, 12.7529) /0.270	0.429
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abnormal dreams						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.525
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Depression						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
<100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Libido decreased						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nervousness						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Stress <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acute stress disorder						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anxiety disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intentional self-injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Paranoia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	15/227 (7%)	20/227 (9%)	0.7323 (0.3650, 1.4693) /0.381	-2.2026 (-7.1057, 2.7004) /0.379	0.7500 (0.3940, 1.4276) /0.381	0.738
>=100,000	3/ 56 (5%)	3/ 56 (5%)	1.0000 (0.1930, 5.1809) />0.999	<0.0001 (-8.3403, 8.3403) />0.999	1.0000 (0.2108, 4.7438) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
<100,000	1/227 (<1%)	5/227 (2%)	0.1965 (0.0228, 1.6950) /0.139	-1.7621 (-3.8568, 0.3325) /0.099	0.2000 (0.0236, 1.6984) /0.140	0.429
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	
Contusion						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Thermal burn <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.305
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Muscle strain						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penis injury <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Procedural pain <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bone contusion <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cranio-cerebral injury						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Epicondylitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Foot fracture						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Heat stroke <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ligament sprain <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Multiple injuries <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Penile contusion <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural haemorrhage <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Traumatic haematoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral injury						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Wound						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<100,000	19/227 (8%)	11/227 (5%)	1.7937 (0.8333, 3.8608) /0.135	3.5242 (-1.0345, 8.0829) /0.130	1.7273 (0.8412, 3.5465) /0.136	0.985
>=100,000	7/ 56 (13%)	4/ 56 (7%)	1.8571 (0.5117, 6.7396) /0.347	5.3571 (-5.6213, 16.3356) /0.339	1.7500 (0.5424, 5.6458) /0.349	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<100,000	15/227 (7%)	8/227 (4%)	1.9369 (0.8045, 4.6632) /0.140	3.0837 (-0.9409, 7.1083) /0.133	1.8750 (0.8110, 4.3350) /0.142	0.594
>=100,000	6/ 56 (11%)	2/ 56 (4%)	3.2400 (0.6248, 16.8013) /0.162	7.1429 (-2.3042, 16.5899) /0.138	3.0000 (0.6324, 14.2315) /0.167	
Hypovitaminosis						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypertriglyceridaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glucose tolerance impaired						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperlipasaemia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypocalcaemia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypokalaemia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypomagnesaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypophosphataemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Iron deficiency						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lactose intolerance						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Type 2 diabetes mellitus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	13/227 (6%)	14/227 (6%)	0.9242 (0.4244, 2.0129) /0.843	-0.4405 (-4.7914, 3.9103) /0.843	0.9286 (0.4465, 1.9310) /0.843	0.165
>=100,000	4/ 56 (7%)	1/ 56 (2%)	4.2308 (0.4577, 39.1046) /0.204	5.3571 (-2.2277, 12.9419) /0.166	4.0000 (0.4614, 34.6768) /0.208	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<100,000	7/227 (3%)	3/227 (1%)	2.3758 (0.6066, 9.3050) /0.214	1.7621 (-0.9332, 4.4574) /0.200	2.3333 (0.6110, 8.9105) /0.215	0.670
>=100,000	4/ 56 (7%)	1/ 56 (2%)	4.2308 (0.4577, 39.1046) /0.204	5.3571 (-2.2277, 12.9419) /0.166	4.0000 (0.4614, 34.6768) /0.208	
Skin papilloma						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Melanocytic naevus <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral papilloma						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Uterine leiomyoma						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign spleen tumour						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dysplastic naevus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Neoplasm skin <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral fibroma <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	15/227 (7%)	8/227 (4%)	1.9369 (0.8045, 4.6632) /0.140	3.0837 (-0.9409, 7.1083) /0.133	1.8750 (0.8110, 4.3350) /0.142	0.887
>=100,000	5/ 56 (9%)	3/ 56 (5%)	1.7320 (0.3935, 7.6246) /0.468	3.5714 (-5.9448, 13.0877) /0.462	1.6667 (0.4182, 6.6421) /0.469	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	3/ 56 (5%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	0.542
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Blood glucose abnormal						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Carbon dioxide decreased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Electrocardiogram QT prolonged <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram repolarisation abnormality <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Haemoglobin decreased <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heart rate increased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nuclear magnetic resonance imaging brain abnormal						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Protein urine present						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Total lung capacity decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Weight increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<100,000	9/227 (4%)	13/227 (6%)	0.6796 (0.2846, 1.6231) /0.385	-1.7621 (-5.7092, 2.1850) /0.382	0.6923 (0.3020, 1.5873) /0.385	0.011
>=100,000	4/ 56 (7%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Erectile dysfunction						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Breast mass						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital lesion						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Prostatitis						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast discharge						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Breast pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervix disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dysfunctional uterine bleeding						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Menopausal symptoms <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Polymenorrhoea						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vaginal dysplasia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vaginal ulceration <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicocele <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvar dysplasia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal pruritus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<100,000	9/227 (4%)	6/227 (3%)	1.5206 (0.5322, 4.3446) /0.434	1.3216 (-1.9645, 4.6076) /0.431	1.5000 (0.5428, 4.1452) /0.434	0.566
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia <100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	0.130
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Leukocytosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Normocytic anaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Splenomegaly						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<100,000	10/227 (4%)	3/227 (1%)	3.4409 (0.9343, 12.6716) /0.063	3.0837 (0.0286, 6.1388) /0.048	3.3333 (0.9296, 11.9532) /0.065	0.023
>=100,000	1/ 56 (2%)	4/ 56 (7%)	0.2364 (0.0256, 2.1847) /0.204	-5.3571 (-12.9419, 2.2277) /0.166	0.2500 (0.0288, 2.1673) /0.208	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
<100,000	5/227 (2%)	1/227 (<1%)	5.0901 (0.5900, 43.9170) /0.139	1.7621 (-0.3325, 3.8568) /0.099	5.0000 (0.5888, 42.4604) /0.140	0.084
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Haematuria						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Calculus urinary						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Micturition urgency						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nephropathy						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Proteinuria <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral caruncle						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urethral discharge						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral pain <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Urinary incontinence <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<100,000	6/227 (3%)	7/227 (3%)	0.8533 (0.2822, 2.5795) /0.779	-0.4405 (-3.5085, 2.6274) /0.778	0.8571 (0.2926, 2.5109) /0.779	0.093
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Asthenopia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Astigmatism <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blepharospasm <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dry eye						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye irritation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye pain						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Glare <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Meibomian gland dysfunction						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Myopia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Uveitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous detachment						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<100,000	6/227 (3%)	3/227 (1%)	2.0271 (0.5007, 8.2066) /0.322	1.3216 (-1.2400, 3.8832) /0.312	2.0000 (0.5064, 7.8994) /0.323	0.152
>=100,000	1/ 56 (2%)	3/ 56 (5%)	0.3212 (0.0324, 3.1859) /0.332	-3.5714 (-10.4133, 3.2704) /0.306	0.3333 (0.0357, 3.1082) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.409
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vertigo positional						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Deafness						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective myringitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tinnitus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<100,000	8/227 (4%)	2/227 (<1%)	4.1096 (0.8630, 19.5689) /0.076	2.6432 (-0.0460, 5.3323) /0.054	4.0000 (0.8588, 18.6309) /0.077	0.637
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	0.389
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypersensitivity						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Mite allergy <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	0.130
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.187
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hot flush <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperaemia <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Intermittent claudication <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Atrioventricular block first degree						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gilbert's syndrome						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Keratosis follicular						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypogonadism						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidis m						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatitis toxic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-alcoholic steatohepatitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tooth extraction						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	118/227 (52%)	74/227 (33%)	2.2383 (1.5298, 3.2748) /<.001	19.3833 (10.4713, 28.2952) /<.001	1.5946 (1.2733, 1.9969) /<.001	0.257
>=100,000	25/ 56 (45%)	21/ 56 (38%)	1.3441 (0.6316, 2.8601) /0.443	7.1429 (-11.0313, 25.3170) /0.441	1.1905 (0.7617, 1.8606) /0.444	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<100,000	46/227 (20%)	40/227 (18%)	1.1881 (0.7423, 1.9018) /0.473	2.6432 (-4.5616, 9.8479) /0.472	1.1500 (0.7851, 1.6845) /0.473	0.861
>=100,000	10/ 56 (18%)	8/ 56 (14%)	1.3043 (0.4732, 3.5950) /0.607	3.5714 (-10.0160, 17.1589) /0.606	1.2500 (0.5328, 2.9325) /0.608	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<100,000	5/227 (2%)	3/227 (1%)	1.6817 (0.3971, 7.1216) /0.480	0.8811 (-1.5381, 3.3002) /0.475	1.6667 (0.4031, 6.8916) /0.481	0.747
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<100,000	3/227 (1%)	4/227 (2%)	0.7467 (0.1652, 3.3744) /0.704	-0.4405 (-2.7069, 1.8258) /0.703	0.7500 (0.1698, 3.3132) /0.704	0.288
>=100,000	3/ 56 (5%)	1/ 56 (2%)	3.1132 (0.3139, 30.8783) /0.332	3.5714 (-3.2704, 10.4133) /0.306	3.0000 (0.3217, 27.9738) /0.335	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	0.263
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastroenteritis <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory tract infection viral <100,000	1/227 (<1%)	4/227 (2%)	0.2467 (0.0274, 2.2243) /0.212	-1.3216 (-3.2377, 0.5946) /0.176	0.2500 (0.0282, 2.2195) /0.213	0.103
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Rhinitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Syphilis						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <100,000	3/227 (1%)	4/227 (2%)	0.7467 (0.1652, 3.3744) /0.704	-0.4405 (-2.7069, 1.8258) /0.703	0.7500 (0.1698, 3.3132) /0.704	0.857
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Folliculitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tonsillitis						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.187
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Oral herpes <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Conjunctivitis						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gastroenteritis viral <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urinary tract infection						
<100,000	1/227 (<1%)	3/227 (1%)	0.3304 (0.0341, 3.2002) /0.339	-0.8811 (-2.5984, 0.8362) /0.315	0.3333 (0.0349, 3.1806) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Herpes zoster						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urethritis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Sinusitis						
<100,000	0/227	3/227 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Oropharyngeal gonococcal infection <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chlamydial infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Genital herpes simplex <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	
Tooth abscess <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheobronchitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urethritis gonococcal						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Proctitis chlamydial <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acarodermatitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Orchitis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acute hepatitis C <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pneumonia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Abscess						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Erysipelas						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Genital candidiasis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary chlamydia infection						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genitourinary tract gonococcal infection						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatitis E <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphogranulo ma venereum						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Malaria						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pharyngeal chlamydia infection <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post procedural infection						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Urethritis mycoplasmal <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vulvovaginal mycotic infection <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<100,000	80/227 (35%)	4/227 (2%)	30.3401 (10.8800, 84.6069) /<.001	33.4802 (27.0342, 39.9262) /<.001	20.0000 (7.4525, 53.6735) /<.001	NC
>=100,000	16/ 56 (29%)	0/ 56	>999 (>999, >999) /NC	29.6148 (0.7715, 58.4581) /0.044	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
<100,000	78/227 (34%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	14/ 56 (25%)	0/ 56	>999 (>999, >999) /NC	26.2170 (-2.4668, 54.9008) /0.073	>999 (>999, >999) /NC	
Injection site nodule						
<100,000	5/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site swelling						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pyrexia						
<100,000	4/227 (2%)	2/227 (<1%)	2.0179 (0.3659, 11.1287) /0.420	0.8811 (-1.2183, 2.9804) /0.411	2.0000 (0.3700, 10.8106) /0.421	0.242
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Influenza like illness						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Fatigue						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Asthenia						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site warmth						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site bruising <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site haematoma <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Injection site discolouration <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Catheter site erythema <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	29/227 (13%)	7/227 (3%)	4.6032 (1.9726, 10.7420) /<.001	9.6916 (4.8013, 14.5819) /<.001	4.1428 (1.8529, 9.2627) /<.001	0.053
>=100,000	5/ 56 (9%)	5/ 56 (9%)	1.0000 (0.2728, 3.6654) />0.999	<0.0001 (-10.5621, 10.5621) />0.999	1.0000 (0.3064, 3.2640) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <100,000	10/227 (4%)	2/227 (<1%)	5.1843 (1.1231, 23.9324) /0.035	3.5242 (0.5909, 6.4576) /0.019	5.0000 (1.1079, 22.5657) /0.036	0.195
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Abdominal pain						
<100,000	4/227 (2%)	1/227 (<1%)	4.0538 (0.4496, 36.5528) /0.212	1.3216 (-0.5946, 3.2377) /0.176	4.0000 (0.4506, 35.5117) /0.213	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Dyspepsia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vomiting <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	0.187
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation <100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Abdominal pain upper <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastritis						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Flatulence <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Haemorrhoidal haemorrhage <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal inflammation						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Faeces soft <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Inguinal hernia <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Diarrhoea haemorrhagic						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Barrett's oesophagus <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Pancreatitis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Paraesthesia oral						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tooth development disorder						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	14/227 (6%)	8/227 (4%)	1.7993 (0.7397, 4.3767) /0.195	2.6432 (-1.2998, 6.5861) /0.189	1.7500 (0.7488, 4.0901) /0.196	0.603
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <100,000	7/227 (3%)	4/227 (2%)	1.7739 (0.5120, 6.1452) /0.366	1.3216 (-1.5045, 4.1477) /0.359	1.7500 (0.5194, 5.8958) /0.367	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Myalgia <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.409
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle spasms <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Pain in extremity						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteochondrosis						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Osteoarthritis						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Osteoporosis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Temporomandibular joint syndrome						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<100,000	15/227 (7%)	7/227 (3%)	2.2237 (0.8891, 5.5619) /0.088	3.5242 (-0.4129, 7.4614) /0.079	2.1428 (0.8905, 5.1563) /0.089	0.242
>=100,000	1/ 56 (2%)	2/ 56 (4%)	0.4909 (0.0432, 5.5742) /0.566	-1.7857 (-7.7569, 4.1855) /0.558	0.5000 (0.0467, 5.3578) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache <100,000	10/227 (4%)	4/227 (2%)	2.5691 (0.7938, 8.3150) /0.115	2.6432 (-0.5279, 5.8143) /0.102	2.5000 (0.7957, 7.8549) /0.117	0.420
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dizziness <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Migraine <100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Syncope						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
≥100,000	0/ 56	0/ 56	NC	NC	NC	
Amnesia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
≥100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Neuropathy peripheral <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria <100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anosmia <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical neuritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nerve compression						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculitis brachial						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Trigeminal neuralgia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<100,000	6/227 (3%)	6/227 (3%)	1.0000 (0.3176, 3.1482) />0.999	<0.0001 (-2.9512, 2.9512) />0.999	1.0000 (0.3274, 3.0542) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Rash						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.187
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperhidrosis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Dyshidrotic eczema						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Urticaria						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dandruff <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nail pigmentation <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash morbilliform						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<100,000	13/227 (6%)	6/227 (3%)	2.2375 (0.8352, 5.9943) /0.109	3.0837 (-0.5893, 6.7567) /0.100	2.1667 (0.8382, 5.6006) /0.111	0.136
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cough						
<100,000	5/227 (2%)	2/227 (<1%)	2.5338 (0.4865, 13.1970) /0.270	1.3216 (-0.9419, 3.5850) /0.252	2.5000 (0.4901, 12.7529) /0.270	0.136
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Oropharyngeal pain						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Catarrh						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Asthma						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Nasal turbinate hypertrophy						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<100,000	10/227 (4%)	7/227 (3%)	1.4483 (0.5414, 3.8741) /0.461	1.3216 (-2.1690, 4.8122) /0.458	1.4286 (0.5535, 3.6872) /0.461	0.406
>=100,000	1/ 56 (2%)	2/ 56 (4%)	0.4909 (0.0432, 5.5742) /0.566	-1.7857 (-7.7569, 4.1855) /0.558	0.5000 (0.0467, 5.3578) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	0.206
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Insomnia <100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Libido decreased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Panic attack						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Affective disorder						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Major depression <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	9/227 (4%)	10/227 (4%)	0.8959 (0.3570, 2.2479) /0.815	-0.4405 (-4.1243, 3.2432) /0.815	0.9000 (0.3727, 2.1732) /0.815	0.922
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Contusion						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Arthropod sting <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fall						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ligament sprain						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Wound <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ankle fracture						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Meniscus injury						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure via inhalation						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Fracture						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Joint injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Sunburn <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon injury <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Tibia fracture <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<100,000	4/227 (2%)	6/227 (3%)	0.6607 (0.1839, 2.3733) /0.525	-0.8811 (-3.5800, 1.8179) /0.522	0.6667 (0.1907, 2.3309) /0.525	0.793
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypercholesterolaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Diabetes mellitus						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Lipoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal neoplasm <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Breast cancer <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Kidney angiolipoma						
^a <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	10/227 (4%)	12/227 (5%)	0.8257 (0.3493, 1.9514) /0.662	-0.8811 (-4.8307, 3.0686) /0.662	0.8333 (0.3675, 1.8898) /0.663	0.215
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.275
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Glomerular filtration rate decreased						
<100,000	0/227	3/227 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Weight decreased						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aortic bruit <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blood cholesterol increased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood folate decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Low density lipoprotein increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma test positive						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Platelet count decreased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Treponema test positive						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.817
>=100,000	2/ 56 (4%)	2/ 56 (4%)	1.0000 (0.1359, 7.3590) />0.999	<0.0001 (-6.8737, 6.8737) />0.999	1.0000 (0.1459, 6.8527) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Erectile dysfunction						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Prostatitis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstruation irregular						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ovarian cyst						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Testicular pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<100,000	2/227 (<1%)	2/227 (<1%)	1.0000 (0.1396, 7.1610) />0.999	<0.0001 (-1.7192, 1.7192) />0.999	1.0000 (0.1421, 7.0379) />0.999	0.146
>=100,000	0/ 56	2/ 56 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8004 (-33.0877, 21.4869) /0.677	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Eosinophilia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypochromic anaemia						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Renal failure <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	0.476
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cataract						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Chorioretinal disorder <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic retinopathy						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye allergy						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glaucoma						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Ear and labyrinth disorders						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.206
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension <100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	
Circulatory collapse <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Peripheral artery thrombosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Thrombophlebitis superficial						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cardiovascular disorder						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Goitre						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperbilirubi naemia						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic steatosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hydrocholecystis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	20/227 (9%)	8/227 (4%)	2.6449 (1.1400, 6.1367) /0.024	5.2863 (0.8875, 9.6852) /0.019	2.5000 (1.1244, 5.5583) /0.025	0.608
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<100,000	1/227 (<1%)	2/227 (<1%)	0.4978 (0.0448, 5.5287) /0.570	-0.4405 (-1.9305, 1.0495) /0.562	0.5000 (0.0457, 5.4753) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal abscess						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatitis A						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.042
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
<100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vertebral foraminal stenosis <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Poor quality sleep						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Night sweats						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Suicide attempt						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Multiple injuries						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Post lumbar puncture syndrome						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hypophosphataemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin cancer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	4/227 (2%)	3/227 (1%)	1.3393 (0.2963, 6.0529) /0.704	0.4405 (-1.8258, 2.7069) /0.703	1.3333 (0.3018, 5.8901) /0.704	0.857
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	0.305
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Alanine aminotransferase increased <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Blood triglycerides increased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bile duct stone						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cholecystitis <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatic cirrhosis <100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	6/227 (3%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.115
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatitis A						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Rectal fissure						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Road traffic accident <100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Diabetic ketoacidosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased <100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Lipase increased <100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Induction BL HIV-1 RNA (c/mL) - FLAIR

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Weight decreased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	15/143 (10%)	5/145 (3%)	3.2812 (1.1596, 9.2844) /0.025	7.0412 (1.2066, 12.8759) /0.018	3.0420 (1.1355, 8.1491) /0.027	0.841
35-<50	12/107 (11%)	4/109 (4%)	3.3158 (1.0341, 10.6314) /0.044	7.5452 (0.6022, 14.4883) /0.033	3.0561 (1.0176, 9.1782) /0.046	
>=50	4/ 33 (12%)	2/ 29 (7%)	1.8621 (0.3151, 11.0029) /0.493	5.2247 (-9.2340, 19.6833) /0.479	1.7576 (0.3470, 8.9026) /0.496	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	4/143 (3%)	1/145 (<1%)	4.1439 (0.4575, 37.5359) /0.206	2.1075 (-0.9121, 5.1272) /0.171	4.0559 (0.4589, 35.8478) /0.208	0.681
35-<50	4/107 (4%)	2/109 (2%)	2.0777 (0.3725, 11.5889) /0.404	1.9035 (-2.4860, 6.2929) /0.395	2.0374 (0.3811, 10.8912) /0.405	
>=50	1/ 33 (3%)	1/ 29 (3%)	0.8750 (0.0523, 14.6479) /0.926	-0.4180 (-9.2672, 8.4312) /0.926	0.8788 (0.0575, 13.4279) /0.926	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	8/143 (6%)	1/145 (<1%)	8.5333 (1.0533, 69.1345) /0.045	4.9048 (0.9045, 8.9050) /0.016	8.1119 (1.0277, 64.0275) /0.047	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	8/143 (6%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<35	2/143 (1%)	2/145 (1%)	1.0142 (0.1409, 7.2995) /0.989	0.0193 (-2.6841, 2.7227) /0.989	1.0140 (0.1448, 7.1007) /0.989	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	1/109 (<1%)	1.0189 (0.0629, 16.5010) /0.990	0.0171 (-2.5378, 2.5721) /0.990	1.0187 (0.0645, 16.0782) /0.990	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
<hr/>						
Multiple injuries <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin cancer						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	3/ 63 (5%)	2/ 64 (3%)	1.5500 (0.2501, 9.6053) /0.638	1.6369 (-5.1325, 8.4063) /0.636	1.5238 (0.2635, 8.8133) /0.638	0.475
Male	28/220 (13%)	9/219 (4%)	3.4028 (1.5660, 7.3941) /0.002	8.6177 (3.4886, 13.7467) /<.001	3.0970 (1.4964, 6.4094) /0.002	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	3/ 63 (5%)	1/ 64 (2%)	3.1500 (0.3188, 31.1253) /0.326	3.1994 (-2.8739, 9.2727) /0.302	3.0476 (0.3257, 28.5210) /0.329	0.747
Male	6/220 (3%)	3/219 (1%)	2.0187 (0.4984, 8.1759) /0.325	1.3574 (-1.2888, 4.0036) /0.315	1.9909 (0.5043, 7.8602) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	3/220 (1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	
Weight decreased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	11/220 (5%)	1/219 (<1%)	11.4737 (1.4684, 89.6530) /0.020	4.5434 (1.5282, 7.5586) /0.003	10.9500 (1.4259, 84.0898) /0.021	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Injection site pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	11/220 (5%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Systemic inflammatory response syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	2/219 (<1%)	1.5000 (0.2482, 9.0660) /0.659	0.4504 (-1.5335, 2.4343) /0.656	1.4932 (0.2520, 8.8489) /0.659	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	
Acute hepatitis B						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	2/219 (<1%)	0.4954 (0.0446, 5.5039) /0.568	-0.4587 (-2.0006, 1.0832) /0.560	0.4977 (0.0455, 5.4491) /0.568	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Multiple injuries						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post lumbar puncture syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Road traffic accident						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperlipasemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Large intestine perforation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cholecystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertebral foraminal stenosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adenocarcinoma of colon						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin cancer						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	27/216 (13%)	9/201 (4%)	3.0476 (1.3961, 6.6527) /0.005	8.0224 (2.7663, 13.2784) /0.003	2.7917 (1.3460, 5.7902) /0.006	0.867
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	9/216 (4%)	3/201 (1%)	2.8696 (0.7657, 10.7536) /0.118	2.6741 (-0.4741, 5.8224) /0.096	2.7917 (0.7666, 10.1664) /0.120	0.135
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.221
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	3/216 (1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Creatinine renal clearance decreased						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hepatic enzyme increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Weight decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	9/216 (4%)	1/201 (<1%)	8.6956 (1.0917, 69.2629) /0.041	3.6692 (0.8323, 6.5060) /0.011	8.3750 (1.0706, 65.5153) /0.043	0.491
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	9/216 (4%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 67 (3%)	0/ 80	>999 (>999, >999) /NC	5.2349 (-17.7448, 28.2147) /0.655	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Systemic inflammatory response syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	2/216 (<1%)	2/201 (<1%)	0.9299 (0.1298, 6.6644) /0.942	-0.0691 (-1.9437, 1.8055) /0.942	0.9306 (0.1323, 6.5440) /0.942	0.236
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Acute hepatitis B						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Multiple injuries						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post lumbar puncture syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Road traffic accident						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	0.268
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diabetic ketoacidosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hyperlipasemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Colitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Large intestine perforation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Cholecystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Vertebral foraminal stenosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adenocarcinoma of colon						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Skin cancer						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	4/ 47 (9%)	3/ 62 (5%)	1.8295 (0.3892, 8.5994) /0.444	3.6719 (-5.9286, 13.2724) /0.453	1.7589 (0.4133, 7.4844) /0.445	0.639
Europe	26/213 (12%)	7/192 (4%)	3.6745 (1.5565, 8.6746) /0.003	8.5607 (3.4269, 13.6945) /0.001	3.3481 (1.4872, 7.5373) /0.004	
Rest of World	1/ 23 (4%)	1/ 29 (3%)	1.2727 (0.0753, 21.5130) /0.867	0.8996 (-9.7570, 11.5561) /0.869	1.2609 (0.0833, 19.0877) /0.867	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	0.270
Europe	8/213 (4%)	2/192 (1%)	3.7073 (0.7775, 17.6779) /0.100	2.7142 (-0.2153, 5.6437) /0.069	3.6056 (0.7752, 16.7712) /0.102	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	10/213 (5%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	10/213 (5%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Multiple injuries						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post lumbar puncture syndrome						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertebral foraminal stenosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin cancer						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	26/227 (11%)	8/227 (4%)	3.5410 (1.5671, 8.0016) /0.002	7.9295 (3.1424, 12.7166) /0.001	3.2500 (1.5036, 7.0246) /0.003	0.418
>=100,000	5/ 56 (9%)	3/ 56 (5%)	1.7320 (0.3935, 7.6246) /0.468	3.5714 (-5.9448, 13.0877) /0.462	1.6667 (0.4182, 6.6421) /0.469	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	7/227 (3%)	3/227 (1%)	2.3758 (0.6066, 9.3050) /0.214	1.7621 (-0.9332, 4.4574) /0.200	2.3333 (0.6110, 8.9105) /0.215	0.912
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class	Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased							
	<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	0.187
	>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<100,000	3/227 (1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Creatinine renal clearance decreased						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hepatic enzyme increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Weight decreased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.042
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Injection site pain						
<100,000	10/227 (4%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<100,000	3/227 (1%)	2/227 (<1%)	1.5067 (0.2494, 9.1034) /0.655	0.4405 (-1.4790, 2.3601) /0.653	1.5000 (0.2530, 8.8922) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Acute hepatitis B						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class	Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess							
	<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
	>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.305
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Multiple injuries						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post lumbar puncture syndrome						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Road traffic accident						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal column injury						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<100,000	2/227 (<1%)	1/227 (<1%)	2.0089 (0.1809, 22.3120) /0.570	0.4405 (-1.0495, 1.9305) /0.562	2.0000 (0.1826, 21.9012) /0.570	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diabetic ketoacidosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hyperlipasemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypophosphataemia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Large intestine perforation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Cholecystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class	Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic cirrhosis	<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
	>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Vertebral foraminal stenosis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adenocarcinoma of colon						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Skin cancer						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Poor quality sleep						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Suicide attempt						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	5/143 (3%)	6/145 (4%)	0.8394 (0.2503, 2.8147) /0.777	-0.6414 (-5.0656, 3.7827) /0.776	0.8450 (0.2638, 2.7066) /0.777	0.466
35-<50	9/107 (8%)	4/109 (4%)	2.4107 (0.7192, 8.0805) /0.154	4.7415 (-1.5922, 11.0752) /0.142	2.2921 (0.7278, 7.2184) /0.156	
>=50	4/ 33 (12%)	2/ 29 (7%)	1.8621 (0.3151, 11.0029) /0.493	5.2247 (-9.2340, 19.6833) /0.479	1.7576 (0.3470, 8.9026) /0.496	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	1/143 (<1%)	3/145 (2%)	0.3333 (0.0343, 3.2429) /0.344	-1.3697 (-4.0591, 1.3198) /0.318	0.3380 (0.0356, 3.2112) /0.345	0.344
35-<50	3/107 (3%)	1/109 (<1%)	3.1154 (0.3189, 30.4318) /0.328	1.8863 (-1.7175, 5.4901) /0.305	3.0561 (0.3229, 28.9199) /0.330	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	NC
>=50	0/ 33	0/ 29	NC	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	2/107 (2%)	1/109 (<1%)	2.0571 (0.1838, 23.0290) /0.558	0.9517 (-2.1770, 4.0804) /0.551	2.0374 (0.1875, 22.1371) /0.559	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anal fistula						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Colitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	2/ 29 (7%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	1/143 (<1%)	1/145 (<1%)	1.0141 (0.0628, 16.3703) /0.992	0.0096 (-1.9087, 1.9280) /0.992	1.0140 (0.0640, 16.0556) /0.992	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cancer						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kaposi's sarcoma						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	1/ 29 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	2/109 (2%)	0.5047 (0.0451, 5.6501) /0.579	-0.9003 (-4.0102, 2.2097) /0.570	0.5093 (0.0469, 5.5343) /0.579	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tibia fracture						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bile duct stone						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocholecystis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	NC
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reproductive system and breast disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	1/ 63 (2%)	3/ 64 (5%)	0.3280 (0.0332, 3.2405) /0.340	-3.1002 (-9.1286, 2.9282) /0.313	0.3386 (0.0362, 3.1690) /0.343	0.124
Male	17/220 (8%)	9/219 (4%)	1.9540 (0.8515, 4.4842) /0.114	3.6177 (-0.7826, 8.0180) /0.107	1.8803 (0.8568, 4.1265) /0.115	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	4/219 (2%)	0.9954 (0.2458, 4.0312) /0.995	-0.0083 (-2.5108, 2.4942) /0.995	0.9955 (0.2521, 3.9301) /0.995	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	3/220 (1%)	1/219 (<1%)	3.0138 (0.3111, 29.2001) /0.341	0.9070 (-0.8667, 2.6807) /0.316	2.9864 (0.3131, 28.4879) /0.342	
Anal abscess						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gastroenteritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Viral infection						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	4/220 (2%)	1/219 (<1%)	4.0370 (0.4476, 36.4114) /0.214	1.3616 (-0.6169, 3.3400) /0.177	3.9818 (0.4486, 35.3409) /0.215	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal fistula						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterocolitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Large intestine perforation						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal fissure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Umbilical hernia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.278
Male	2/220 (<1%)	2/219 (<1%)	0.9954 (0.1390, 7.1303) /0.996	-0.0042 (-1.7819, 1.7736) /0.996	0.9955 (0.1415, 7.0038) /0.996	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	
Adenocarcinoma of colon						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	
Kaposi's sarcoma						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	0.308
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Road traffic accident						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tibia fracture						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Systemic inflammatory response syndrome						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Drug abuse						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Suicide attempt						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bile duct stone						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hydrocholecystitis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vascular disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral artery thrombosis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Peripheral ischaemia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	14/216 (6%)	10/201 (5%)	1.3238 (0.5742, 3.0518) /0.510	1.5064 (-2.9451, 5.9578) /0.507	1.3028 (0.5922, 2.8661) /0.511	0.511
Non-White	4/ 67 (6%)	2/ 80 (3%)	2.4762 (0.4392, 13.9610) /0.304	3.4701 (-3.1549, 10.0952) /0.305	2.3881 (0.4513, 12.6358) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	3/216 (1%)	4/201 (2%)	0.6937 (0.1533, 3.1382) /0.635	-0.6012 (-3.0838, 1.8815) /0.635	0.6979 (0.1581, 3.0800) /0.635	0.179
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	0.366
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Anal abscess						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Gastroenteritis						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Viral infection						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	3/216 (1%)	1/201 (<1%)	2.8169 (0.2906, 27.3037) /0.372	0.8914 (-0.9476, 2.7304) /0.342	2.7917 (0.2928, 26.6195) /0.372	0.433
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal fistula						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Colitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Enterocolitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Large intestine perforation						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Rectal fissure						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Umbilical hernia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	2/216 (<1%)	3/201 (1%)	0.6168 (0.1020, 3.7301) /0.599	-0.5666 (-2.6741, 1.5408) /0.598	0.6204 (0.1047, 3.6745) /0.599	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	
Adenocarcinoma of colon						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cancer						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Kaposi's sarcoma						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	1/216 (<1%)	2/201 (<1%)	0.4628 (0.0416, 5.1434) /0.531	-0.5321 (-2.1759, 1.1118) /0.526	0.4653 (0.0425, 5.0918) /0.531	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Road traffic accident						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tibia fracture						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pyrexia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Systemic inflammatory response syndrome						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	-4.7645 (-29.5248, 19.9959) /0.706	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Drug abuse						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	
Suicide attempt						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Bile duct stone						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cholecystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Hydrocholecystitis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Weight decreased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
White	0/216	0/201	NC	NC	NC	NC
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral artery thrombosis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Peripheral ischaemia						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	2/ 47 (4%)	4/ 62 (6%)	0.6444 (0.1129, 3.6770) /0.621	-2.1963 (-10.6043, 6.2117) /0.609	0.6596 (0.1261, 3.4499) /0.622	0.170
Europe	14/213 (7%)	8/192 (4%)	1.6181 (0.6635, 3.9461) /0.290	2.4061 (-1.9601, 6.7723) /0.280	1.5775 (0.6766, 3.6777) /0.291	
Rest of World	2/ 23 (9%)	0/ 29	>999 (>999, >999) /NC	10.6982 (-28.2336, 49.6299) /0.590	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	3/213 (1%)	4/192 (2%)	0.6714 (0.1484, 3.0389) /0.605	-0.6749 (-3.2412, 1.8914) /0.606	0.6761 (0.1533, 2.9823) /0.605	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 47 (2%)	1/ 62 (2%)	1.3261 (0.0808, 21.7657) /0.843	0.5148 (-4.6672, 5.6967) /0.846	1.3191 (0.0847, 20.5478) /0.843	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine perforation						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal fissure						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/213 (<1%)	2/192 (1%)	0.9005 (0.1256, 6.4553) /0.917	-0.1027 (-2.0366, 1.8312) /0.917	0.9014 (0.1282, 6.3372) /0.917	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital warts						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kaposi's sarcoma						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laceration						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tibia fracture						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Systemic inflammatory response syndrome						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
North America	0/ 47	1/ 62 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8907 (-33.3898, 25.6084) /0.796	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bile duct stone						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Hydrocholecystis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
North America	1/ 47 (2%)	0/ 62	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/213	0/192	NC	NC	NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral ischaemia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	12/227 (5%)	9/227 (4%)	1.3519 (0.5582, 3.2743) /0.504	1.3216 (-2.5406, 5.1838) /0.502	1.3333 (0.5731, 3.1023) /0.504	0.611
>=100,000	6/ 56 (11%)	3/ 56 (5%)	2.1200 (0.5029, 8.9368) /0.306	5.3571 (-4.6630, 15.3773) /0.295	2.0000 (0.5261, 7.6037) /0.309	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<100,000	3/227 (1%)	3/227 (1%)	1.0000 (0.1997, 5.0077) />0.999	<0.0001 (-2.1009, 2.1009) />0.999	1.0000 (0.2040, 4.9022) />0.999	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<100,000	3/227 (1%)	1/227 (<1%)	3.0268 (0.3125, 29.3181) /0.339	0.8811 (-0.8362, 2.5984) /0.315	3.0000 (0.3144, 28.6253) /0.340	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Anal abscess						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis pneumococcal						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Gastroenteritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Viral infection						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.275
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal fistula						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Enterocolitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Large intestine perforation						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal fissure						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Umbilical hernia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	2/227 (<1%)	3/227 (1%)	0.6637 (0.1098, 4.0101) /0.655	-0.4405 (-2.3601, 1.4790) /0.653	0.6667 (0.1125, 3.9521) /0.655	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<100,000	1/227 (<1%)	1/227 (<1%)	1.0000 (0.0622, 16.0857) />0.999	<0.0001 (-1.2184, 1.2184) />0.999	1.0000 (0.0629, 15.8901) />0.999	>0.999
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Adenocarcinoma of colon						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Breast cancer						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Kaposi's sarcoma						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.305
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Laceration						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Road traffic accident						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tibia fracture						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.095
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Systemic inflammatory response syndrome						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<100,000	0/227	2/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Drug abuse						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Bile duct stone						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Hydrocholecystitis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight decreased						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vascular disorders						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral artery thrombosis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Peripheral ischaemia						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
<35	4/143 (3%)	3/145 (2%)	1.3621 (0.2994, 6.1975) /0.689	0.7282 (-2.8315, 4.2880) /0.688	1.3520 (0.3081, 5.9334) /0.689	0.490
35-<50	4/107 (4%)	1/109 (<1%)	4.1942 (0.4611, 38.1515) /0.203	2.8209 (-1.1945, 6.8362) /0.169	4.0748 (0.4629, 35.8673) /0.206	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	3/143 (2%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<35	2/143 (1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	1/ 33 (3%)	0/ 29	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	0/143	0/145	NC	NC	NC	NC
35-<50	2/107 (2%)	0/109	>999 (>999, >999) /NC	4.1459 (-15.4115, 23.7032) /0.678	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Discomfort <35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Fatigue <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	
Nausea						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/143	2/145 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6546 (-20.7395, 13.4303) /0.675	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/143 (<1%)	0/145	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	1/107 (<1%)	0/109	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/143	1/145 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9087 (-20.1545, 14.3370) /0.741	<0.0001 (<0.0001, -) />0.999	NC
35-<50	0/107	0/109	NC	NC	NC	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Age (<35 vs. 35-<50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
<35	0/143	0/145	NC	NC	NC	NC
35-<50	0/107	1/109 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1687 (-23.0077, 16.6703) /0.754	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 33	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	1/ 63 (2%)	1/ 64 (2%)	1.0161 (0.0622, 16.6081) /0.991	0.0248 (-4.3061, 4.3557) /0.991	1.0159 (0.0649, 15.8892) /0.991	0.540
Male	8/220 (4%)	3/219 (1%)	2.7170 (0.7112, 10.3800) /0.144	2.2665 (-0.6470, 5.1800) /0.127	2.6545 (0.7136, 9.8741) /0.145	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	5/220 (2%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Acute hepatitis C						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Secondary syphilis						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	2/220 (<1%)	1/219 (<1%)	2.0000 (0.1800, 22.2187) /0.573	0.4525 (-1.0871, 1.9920) /0.565	1.9909 (0.1819, 21.7964) /0.573	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	2/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	>0.999
Male	1/220 (<1%)	1/219 (<1%)	0.9954 (0.0619, 16.0157) /0.997	-0.0021 (-1.2620, 1.2578) /0.997	0.9955 (0.0627, 15.8145) /0.997	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diarrhoea						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nausea						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	2/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Amnesia						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dizziness						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
Female	1/ 63 (2%)	0/ 64	>999 (>999, >999) /NC	3.8650 (-21.6768, 29.4068) /0.767	>999 (>999, >999) /NC	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	1/220 (<1%)	0/219	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
Female	0/ 63	1/ 64 (2%)	<0.0001 (<0.0001, -) />0.999	-3.8401 (-29.5545, 21.8743) /0.770	<0.0001 (<0.0001, -) />0.999	NC
Male	0/220	0/219	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Gender at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
Female	0/ 63	0/ 64	NC	NC	NC	NC
Male	0/220	1/219 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	8/216 (4%)	2/201 (<1%)	3.8269 (0.8029, 18.2413) /0.092	2.7087 (-0.1594, 5.5767) /0.064	3.7222 (0.7999, 17.3199) /0.094	0.186
Non-White	1/ 67 (1%)	2/ 80 (3%)	0.5909 (0.0524, 6.6635) /0.670	-1.0075 (-5.4946, 3.4797) /0.660	0.5970 (0.0553, 6.4404) /0.671	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	4/216 (2%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 67 (1%)	0/ 80	>999 (>999, >999) /NC	3.7695 (-19.2467, 26.7858) /0.748	>999 (>999, >999) /NC	
Hepatitis A						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Secondary syphilis						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	2/216 (<1%)	1/201 (<1%)	1.8692 (0.1682, 20.7734) /0.611	0.4284 (-1.1771, 2.0339) /0.601	1.8611 (0.1701, 20.3673) /0.611	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	2/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Discomfort						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/216 (<1%)	1/201 (<1%)	0.9302 (0.0578, 14.9718) /0.959	-0.0345 (-1.3633, 1.2942) /0.959	0.9306 (0.0586, 14.7784) /0.959	>0.999
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diarrhoea						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Nausea						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
White	0/216	2/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Amnesia						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Dizziness						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dysarthria						
White	0/216	1/201 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	
Investigations						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
White	1/216 (<1%)	0/201	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 67	0/ 80	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
White	0/216	0/201	NC	NC	NC	NC
Non-White	0/ 67	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5218 (-28.3504, 21.3068) /0.781	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	8/213 (4%)	4/192 (2%)	1.8341 (0.5434, 6.1905) /0.328	1.6725 (-1.5833, 4.9284) /0.314	1.8028 (0.5516, 5.8922) /0.329	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	4/213 (2%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 23 (4%)	0/ 29	>999 (>999, >999) /NC	6.5460 (-31.8364, 44.9285) /0.738	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	1/192 (<1%)	1.8104 (0.1629, 20.1253) /0.629	0.4181 (-1.2293, 2.0656) /0.619	1.8028 (0.1648, 19.7246) /0.629	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	2/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	1/192 (<1%)	0.9009 (0.0560, 14.5034) /0.941	-0.0513 (-1.4223, 1.3196) /0.941	0.9014 (0.0568, 14.3126) /0.941	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	2/192 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	1/213 (<1%)	0/192	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
North America	0/ 47	0/ 62	NC	NC	NC	NC
Europe	0/213	1/192 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 23	0/ 29	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<100,000	6/227 (3%)	2/227 (<1%)	3.0543 (0.6099, 15.2959) /0.174	1.7621 (-0.6530, 4.1772) /0.153	3.0000 (0.6120, 14.7067) /0.176	0.565
>=100,000	3/ 56 (5%)	2/ 56 (4%)	1.5283 (0.2454, 9.5167) /0.649	1.7857 (-5.8565, 9.4280) /0.647	1.5000 (0.2605, 8.6356) /0.650	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations and infestations						
Any Event						
<100,000	4/227 (2%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
<100,000	2/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Secondary syphilis						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	2/ 56 (4%)	1/ 56 (2%)	2.0370 (0.1794, 23.1302) /0.566	1.7857 (-4.1855, 7.7569) /0.558	2.0000 (0.1866, 21.4313) /0.567	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	2/ 56 (4%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	>0.999
>=100,000	1/ 56 (2%)	1/ 56 (2%)	1.0000 (0.0610, 16.3936) />0.999	<0.0001 (-4.9053, 4.9053) />0.999	1.0000 (0.0641, 15.5950) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nausea						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vomiting						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	1/ 56 (2%)	0/ 56	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Disturbance in attention						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	
Dysarthria						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenocarcinoma of colon						
<100,000	1/227 (<1%)	0/227	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	
Suicide attempt						
<100,000	0/227	1/227 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
>=100,000	0/ 56	0/ 56	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - FLAIR

Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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Subgroup: Induction BL (Week -20) HIV-1 RNA (<100,000 vs. >=100,000 c/mL)

System Organ Class Preferred Term	Q4W IM (N=283)	ABC/DTG/3TC (N=283)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal failure						
<100,000	0/227	0/227	NC	NC	NC	NC
>=100,000	0/ 56	1/ 56 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0631 (-31.3340, 23.2077) /0.770	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
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